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No.

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, forecloses a medical necessity defense to the Act's prohibition against manufacturing and distributing marijuana, a Schedule I controlled substance.

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the United States of America, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-11a)[1] is reported at 190 F.3d 1109. The May 13, 1998 memorandum and order of the district court (App. 41a-81a) is reported at 5 F. Supp. 2d 1086. The other opinions and orders of the district court (App. 12a-40a) are unreported.

[1] "App." refers to the separately bound appendix to the petition for a writ of certiorari.

JURISDICTION

The judgment of the court of appeals was entered on September 13, 1999. A petition for rehearing was denied on February 29, 2000 (App. 82a). On May 22, 2000, Justice O'Connor extended the time within which to file a petition for a writ of certiorari to and including June 28, 2000, and on June 19, 2000, Justice O'Connor further extended the time within which to file a petition to and including July 28, 2000. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.*, and Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761, are set forth at App. 83a-92a.

STATEMENT

1. On January 9, 1998, the United States filed suit seeking an injunction against six marijuana distributors and ten associated individuals, alleging that the defendants' ongoing distribution (and in some cases manufacture) of marijuana violated the Controlled Substances Act (CSA).[2] On May 19, 1998, the District Court for the Northern District of California issued a preliminary injunction prohibiting the Oakland Cannabis Buyers' Cooperative and its director (collectively OCBC) and other marijuana distributors from manufacturing and distributing marijuana. App. 39a-40a (order); 41a-81a

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[2] Many such groups formed in the wake of California's Compassionate Use Act, or Proposition 215, passed in November 1996, which purports to authorize the possession and use of marijuana for medical purposes upon a physician's recommendation. See Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West 1999).

(memorandum opinion).[3] On May 21, 1998, OCBC violated the injunction by openly distributing marijuana to numerous persons. *Id.* at 21a-23a. On October 13, 1998, the district court issued an order finding OCBC in civil contempt. *Id.* at 20a-37a. On October 16, 1998, the district court issued an order denying OCBC's motion to modify the injunction to permit marijuana distribution to persons who, in OCBC's view, have a "medical necessity," *i.e.*, persons having a doctor's certificate stating that (1) the person suffers from a serious medical condition; (2) the person would suffer imminent harm if he does not have access to marijuana; (3) marijuana is necessary for treatment of the person's condition or would alleviate the condition or symptoms associated with it; and (4) there is no legal alternative for the effective treatment of the condition because alternative legal drugs are either ineffective or result in intolerable side effects. *Id.* at 19a (denying motion for modification); see also *id.* at 7a-8a, 28a-29a (describing proposed medical necessity defense).

2. In a per curiam opinion, the court of appeals reversed the district court's denial of the motion to modify the injunction to allow the use of marijuana based on asserted medical necessity. App. 1a-11a.[4] The

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[3] In addition to the imposition of criminal and civil penalties for violations of the CSA, see 21 U.S.C. 841-863 (1994 & Supp. IV 1998), the CSA gives district courts jurisdiction to enjoin violations of the Act, 21 U.S.C. 882(a).

[4] The court of appeals also held that it lacked jurisdiction over OCBC's appeal of the district court's denial of a motion to dismiss, App. 2a-5a, and that OCBC's appeal of the district court's order finding it in contempt was moot because the district court on October 30, 1998, vacated its contempt order after OCBC represented to the court that it would comply with the injunction, *id.* at 5a-7a. Those rulings are not at issue here.

court of appeals held that the district court, in construing its equitable power to issue an injunction, erred in not "tak[ing] into account a legally cognizable defense that likely would pertain in the circumstances." *Id.* at 8a. The court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." *Id.* at 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)).

The court of appeals further concluded that the district court abused its discretion in not considering what the court of appeals described as the "strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illness." App. 9a-10a. "Indeed," the court observed, "the City of Oakland has declared a public health emergency" in response to the district court's denial of OCBC's motion to modify the injunction to authorize it to distribute marijuana. *Id.* at 10a. The court also expressed the view that "[t]he evidence in the record is sufficient to justify the requested modification," and the court had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Id.* at 10a. "[B]y contrast," the court continued, the government had identified no "interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing statutes." *Id.* at 11a. The court of appeals therefore remanded the matter to the district court "to reconsider" OCBC's request for a modification of the injunction to allow OCBC to

distribute marijuana to persons who would satisfy OCBC's proposed test of medical necessity. *Ibid.*[5]

3. Following the Ninth Circuit's decision, on May 30, 2000, OCBC filed a motion with the district court to modify the district court's injunction entered on May 19, 1998. On July 17, 2000, the district court granted OCBC's motion. App. 12a-17a. The court explained:

> On remand the government has still not offered any evidence to rebut [OCBC's] evidence that cannabis is medically necessary for a group of seriously ill individuals. Instead, the government continues to press arguments which the Ninth Circuit rejected, including the argument that the Court must find that enjoining the distribution of cannabis to seriously ill individuals is in the public interest because Congress has prohibited such conduct in favor of the administrative process regulating the approval and distribution of drugs.

Id. at 13a. The court therefore stated that, "[a]s a result of the government's failure to offer any new evidence in opposition to [OCBC's] motion, and in light of the Ninth Circuit's opinion, the Court must conclude

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[5] On May 10, 2000, the Ninth Circuit issued an order vacating and remanding the district court's February 25, 1999, order dismissing the counterclaims for injunctive and declaratory relief sought by individual intervenors who alleged that the preliminary injunction violated their asserted substantive due process rights to use cannabis to alleviate their medical conditions. The court of appeals reasoned that, "[a]lthough the substantive claim of violation of Fifth Amendment rights that underlies plaintiffs' claim in this appeal differs from the defense of medical necessity upon which we ruled in the earlier appeal, the injunctive remedy involved in both appeals is similar." *United States* v. *Oakland Cannabis Buyers' Coop.*, No. 99-15838, 2000 WL 569509, at *1 (9th Cir.).

that modifying the injunction as requested is in the public interest" and that it would "exercise its equitable discretion to do so." *Ibid.*

The district court accordingly issued an amended preliminary injunction order, which reaffirmed that OCBC was preliminarily enjoined from manufacturing, distributing, or possessing marijuana with the intent to manufacture or distribute it, in violation of 21 U.S.C. 841(a)(1). App. 15a-16a. The district court further ordered, however, that

> [t]he foregoing injunction does not apply to the distribution of cannabis by [OCBC] to patient-members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or alleviating the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

Id. at 16a-17a.

On July 18, 2000, the district court denied the government's motion for a stay of the court's July 17, 2000, modification order pending appeal.

REASONS FOR GRANTING THE PETITION

The Ninth Circuit has held that medical necessity is a "legally cognizable defense" to a charge of distributing drugs in violation of the Controlled Substances Act. App. 8a. The court has further held that district courts have the "equitable discretion" to fashion an injunction to permit an organization to engage in the ongoing distribution of marijuana, wholly outside the strict controls imposed by the CSA, to individuals claiming a medical necessity for the drug. App. 10a.

The conclusion that a court may exempt certain persons or transactions from the operation of the CSA, based on the view of those persons or the court on whether marijuana has some medical utility, cannot be squared with the judgment Congress itself made in placing marijuana in Schedule I, which applies to substances that have been authoritatively found under the CSA to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). Nor can the court of appeals' decision be squared with Congress's recent statutory declaration that it "continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration." Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. Congress has assigned to the Attorney General and the Secretary of Health and Human Services, under prescribed standards and administrative procedures set forth in the CSA, the responsibility to determine whether the

manufacture and distribution of marijuana and other drugs should be permitted for specified medical purposes. It has not left that determination to individual courts or juries—much less to private organizations like the Oakland Cannabis Buyers' Cooperative.

Whether asserted medical necessity exempts the distribution of marijuana (and other drugs) from strict controls under the CSA is an issue of exceptional and continuing importance. By sanctioning the prospective distribution of marijuana under a common law defense of necessity, the Ninth Circuit's holding flouts the provisions of the CSA banning the distribution of marijuana outside strictly controlled circumstances and undermines the enforcement of the federal drug laws. It also opens the way for producers, distributors, or users of other drugs and devices not approved by the FDA to invoke "medical necessity" as a defense to enforcement of the nation's health and safety laws. The court of appeals' decision therefore warrants this Court's review.

1. a. The court of appeals seriously erred in holding that medical necessity is a defense under the CSA, and in further holding that a district court has the equitable discretion to fashion an injunction that would permit the distribution of marijuana for medicinal purposes wholly outside the strict regulatory regime of the CSA. A common law defense of necessity is available only "when a real legislature would formally do the same under those circumstances." *United States* v. *Schoon*, 971 F.2d 193, 197 (9th Cir. 1991), cert. denied, 504 U.S. 990 (1992). See also 1 Walter LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 629 (1986) ("The defense of necessity is available only in situations wherein the legislature has not itself, in its criminal

statute, made a determination of values. If it has done so, its decision governs.").

The text, structure, and purposes of the CSA all compel the conclusion that Congress expressly has rejected the notion that an individual who claims a medical necessity for marijuana is exempted from the Act's prohibitions on the manufacture, distribution, or dispensing of marijuana. The text of the CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense'" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1); see also *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975). Since the enactment of the CSA in 1970, marijuana has been classified as a Schedule I controlled substance, a classification which means that marijuana has been found to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).

The CSA also establishes a closed system of distribution for Schedule I controlled substances. No physician or pharmacy may dispense a Schedule I controlled substance to any patient outside of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18 and 1301.32; 28 C.F.R. 0.100(b). By contrast, physicians and pharmacies may lawfully distribute controlled substances in Schedules II through V consistent with their DEA registration. 21 U.S.C. 829. Even for substances listed in Schedules II through V, however, the Act does not allow the essentially unregulated manufacture and distribution that the Ninth Circuit has countenanced

for marijuana, a Schedule I controlled substance. See 21 U.S.C. 822-829.

In addition, the CSA establishes an exclusive set of statutory procedures under which controlled substances that have been placed in Schedule I (or any other schedule) may be transferred between, or removed from, the five schedules, based on changes in scientific knowledge. 21 U.S.C. 811(a). Pursuant to that process, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana to a less restrictive schedule may petition the Administrator of the DEA to initiate a rulemaking proceeding to reschedule marijuana. 21 U.S.C. 811(a); 21 C.F.R. 1308.43. The Administrator, acting on behalf of the Attorney General, must refer any rescheduling petition to the Secretary of Health and Human Services for a medical and scientific evaluation, which is binding on the Administrator. 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in the court of appeals. 21 U.S.C. 877; see, *e.g.*, *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994) (upholding Administrator's decision declining to remove marijuana from the list of Schedule I controlled substances). Based on that framework, the courts of appeals uniformly have held that the statutory rescheduling process is the exclusive means by which to challenge marijuana's placement in Schedule I.[6]

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[6] *United States* v. *Burton*, 894 F.2d 188, 192 (6th Cir.), cert. denied, 498 U.S. 857 (1990); *United States* v. *Greene*, 892 F.2d 453, 455-456 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); *United States* v. *Wables*, 731 F.2d 440, 450 (7th Cir. 1984); *United States* v. *Fogarty*, 692 F.2d 542, 548 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); *United States* v. *Middleton*, 690 F.2d 820, 823 (11th

Finally, in a statutory provision enacted in 1998 and entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared that:

> (1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;
>
> * * * * *
>
> (3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana * * *;
>
> (4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act, before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;
>
> (5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;
>
> (6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Kiffer*, 477 F.2d 349, 357 (2d Cir.), cert. denied, 414 U.S. 831 (1973).

* * * * *

> (11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration.

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761 (*reprinted at* App. 89a-92a).[7] That legislation reaffirms Congress's continuing adherence to the existing FDA drug-approval process, and its continuing opposition to any effort to allow the medicinal use of marijuana or other Schedule I controlled substances until they are proven safe and effective based on appropriate findings by the FDA. See, *e.g.*, *Accardi* v. *Pennsylvania R.R. Co.*, 383 U.S. 225, 229 (1966) (continuing purpose of Congress reflected in "sense of Congress" enactment); *Harris* v. *United States*, 359 U.S. 19, 22 n.8 (1959) (continuing purpose of Congress reflected in subsequently-enacted legislation).

Those provisions leave no doubt that, had Congress considered whether an individual claiming a medical need for marijuana could violate the CSA with impunity, Congress would have answered the question

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[7] The legislation was prompted by state initiatives around the country to legalize marijuana for medicinal uses. The provision's sponsor, Representative McCullom, explained that the provision "is important" because, *inter alia*, "[m]ore than 30 States and the District of Columbia have been targeted for possible medical marijuana initiatives," and that such initiatives "have already been passed in California and Arizona." 144 Cong. Rec. H7720 (daily ed. Sept. 15, 1998); see also 144 Cong. Rec. S10,666 (daily ed. Sept. 21, 1998).

with a resounding "no." Yet in recognizing the availability of a medical necessity defense, the court of appeals has sanctioned the use of marijuana for medicinal purposes. That decision is directly at odds with Congress's express finding that marijuana has "no currently accepted medical use." 21 U.S.C. 812(b)(1). It also is inconsistent with the exclusive procedures under the CSA for the removal of marijuana from the list of Schedule I controlled substances in order to allow its use for medical purposes under specified conditions. 21 U.S.C. 811; cf. *United States* v. *Bailey*, 444 U.S. 394, 410 (1980) (noting that a necessity defense is unavailable "if there was a reasonable, legal alternative to violating the law").

Finally, the recognition of a medical necessity defense runs counter to the absolute ban on the distribution of marijuana and other Schedule I controlled substances outside a DEA-registered and FDA-approved research project. 21 U.S.C. 823(f); see also 21 U.S.C. 841(a)(1) (making the distribution and dispensing of controlled substances unlawful "[e]xcept as authorized" by the CSA); *United States* v. *Moore*, 423 U.S. at 131. Indeed, the Ninth Circuit's decision permits the distribution of marijuana under judicial imprimatur without any of the stringent limitations that Congress placed on the manufacture and distribution of controlled substances, even those listed in Schedules II through V. The CSA and the governing regulations require manufacturers, distributors, and dispensers of controlled substances to register with the DEA, 21 U.S.C. 822(a), 823, 21 C.F.R. 1301, and to establish effective controls to guard against the theft and diversion of controlled substances, 21 C.F.R. 1301.71-1301.76; authorize the Attorney General to inspect a registrant's establishment, 21 U.S.C. 822(f),

880; require the Attorney General to determine production quotas for Schedule I and II controlled substances, 21 U.S.C. 826, 21 C.F.R. 1303; impose substantial record-keeping and reporting requirements on registrants, 21 U.S.C. 827, 21 C.F.R. 1304; disallow the distribution of Schedule I and II drugs except pursuant to an order form issued by the DEA, 21 U.S.C. 828, 21 C.F.R. 1305; and establish prescription requirements for the dispensing of controlled substances in Schedules II through V, 21 U.S.C. 829, 21 C.F.R. 1306. The Ninth Circuit's recognition of a medical necessity defense cannot be squared with Congress's considered judgment that the threat to public health and safety mandates a complete ban on the manufacture and distribution of controlled substances outside the express terms of the CSA.

In *United States* v. *Rutherford*, 442 U.S. 544 (1979), this Court considered an analogous issue and held that a claim of medical need for a drug cannot override Congress's judgment that the drug not be distributed absent a finding by the FDA under the statutory framework that the drug is generally recognized by experts as safe and effective. In *Rutherford*, a class of terminally ill cancer patients and their spouses brought suit to enjoin the government from interfering with the interstate shipment and sale of Laetrile, a drug that had not been approved by the FDA under the Food, Drug, and Cosmetic Act (FDCA). The district court granted the requested relief, and the Tenth Circuit affirmed, holding that the safety and effectiveness protections of the FDCA had no reasonable application to terminally ill cancer patients since those patients, by definition, would die of cancer regardless of their treatment. *Id.* at 548-549. The Court unanimously reversed. The Court rejected the Tenth Circuit's

determination that an exemption from the FDCA was justified because the safety and effectiveness standards could have no reasonable application to terminally ill cancer patients, explaining that, "[u]nder our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. * * * Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." *Id.* at 555, 559. The Court also reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is incumbent upon courts to give it effect. *Id.* at 551.

The Court's holding and reasoning in *Rutherford* apply with equal force to the CSA, whose text, structure, and paramount policies evince Congress's intent to ban the distribution of marijuana, even for medicinal purposes. Indeed, every court to have considered the issue has rejected the invocation of a medical necessity defense under the CSA. See *United States* v. *Burton*, 894 F.2d 188, 191 (6th Cir.) (concluding the defense was not available because the defendant could have attempted to participate in a government-approved program to study the effects of marijuana on glaucoma sufferers), cert. denied, 498 U.S. 857 (1990); *United States* v. *Belknap*, No. 92-5363, 1993 WL 30375, at **2 (4th Cir. Feb. 10, 1993) (unpublished) (concluding that there was "no legal or factual basis" for a medical necessity defense to marijuana prosecution); *United States* v. *McWilliams*, No. CR 97-997(A)-GHK (C.D. Cal. Nov. 5, 1999), slip op. 2-3 ("Because Congress has already determined that there is no accepted medical use for marijuana, * * * we conclude as a matter of law that the medical necessity defense is not available

in this case."); *United States* v. *Lederer*, No. CR-97-558 GEB (E.D. Cal. May 21, 1999), slip op. 5-9 ("Since the weighing of values required for the defense of necessity has already been conducted by Congress' proscription of the very acts [the defendant] sought to legitimize through his assertion of the defense, [the defendant's] motion is denied."); *United States* v. *Diana*, No. CR-98-068-RHW (E.D. Wash. Sept. 21, 1998), slip op. 5 (rejecting medical necessity defense because "Congress was aware of the competing interests in cases such as Defendants' and addressed them"); *United States* v. *Allerheilgen*, No. 97-40090-01-DES, 1998 WL 918841 (D. Kan. Nov. 19, 1998) (same).[8]

b. In reaching the contrary holding that medical necessity is a "legally cognizable defense," the court of appeals did not attempt to reconcile a medical necessity defense with either the text of the CSA or the 1998 legislation disapproving any attempt to legalize marijuana for medicinal use outside the existing framework

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[8] State courts that have construed state drug laws are divided on whether a medical necessity defense is available in a marijuana prosecution under those laws. Eight state courts have held that the defense is unavailable. *State* v. *Poling*, No. 26658, 2000 WL 572334, *7-*8 (W. Va. May 8, 2000); *State* v. *Ownbey*, 996 P.2d 510 (Or. Ct. App. 2000); *State* v. *Williams*, 968 P.2d 26 (Wash. Ct. App. 1998), review denied, 984 P.2d 1034 (1999); *Murphy* v. *Commonwealth*, 521 S.E.2d 301, 302-303 (Va. Ct. App. 1999); *State* v. *Tate*, 505 A.2d 941, 946 (N.J. 1986); *State* v. *Cramer*, 851 P.2d 147, 149 (Ariz. Ct. App. 1992); *Kauffman* v. *State*, 620 So. 2d 90, 92-93 (Ala. Crim. App. 1992); *State* v. *Hanson*, 468 N.W.2d 77, 78 (Minn. Ct. App. 1991). By contrast, four state courts have recognized the availability of the defense. See *State* v. *Bachman*, 595 P.2d 287, 288 (Haw. 1979); *State* v. *Hastings*, 801 P.2d 563, 565 (Idaho 1990); *Jenks* v. *State*, 582 So. 2d 676, 678-679 (Fla. Dist. Ct. App.), review denied, 589 So. 2d 292 (1991); *State* v. *Christen*, 704 A.2d 335, 337 (Me. 1997).

of the CSA and the FDCA. Rather, the court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." App. 9a. The court of appeals took the view that the district court abused its discretion first in failing to consider what it deemed the "strong public interest" in the availability of marijuana for medicinal purposes, and second in finding that an injunction against marijuana distribution could not be supported by the government's "general interest in enforcing its statutes." *Id.* at 9a, 11a.

Those conclusions, however, cannot be reconciled with this Court's precedents concerning the limits of a district court's equitable discretion in fashioning an injunction. This Court has long held that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginia Ry. Co.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937). Likewise, in *Hecht Co.* v. *Bowles*, 321 U.S. 321, 331 (1944), the Court held that, where injunctive relief is sought pursuant to a statutory mandate, a court's equitable discretion must reflect the "large objectives" of the statute, "[f]or the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief." This principle was reaffirmed in *TVA* v. *Hill*, 437 U.S. 153, 194 (1978), in which the Supreme Court held that, in examining whether to enter injunctive relief, a court must be mindful that

> it is * * * emphatically * * * the exclusive province of the Congress not only to formulate legislative policies and mandate programs and

> projects, but also to establish their relative priority for the Nation. Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.

See also *Miller* v. *French*, No. 99-224 (June 19, 2000), slip op. 11.

Those principles dictate the conclusion that a district court lacks the discretion, based on its own perception of the public interest and its own weighing of possible medical benefits against the potential for abuse, to craft an injunction under the CSA which exempts from the injunction's reach the distribution of marijuana for medicinal purposes. Congress already has considered the public interest, balanced the relevant medical and other considerations, and concluded that, unless and until the DEA removes marijuana from Schedule I, the drug has no "accepted medical use" and a "high potential for abuse" (21 U.S.C. 812(b)(1)) and may not be manufactured, distributed, or dispensed outside of a program of research approved by the FDA and conducted by a practitioner registered with the DEA (21 U.S.C. 841(a), 823(f)). The Ninth Circuit therefore plainly erred in holding that a district court has the equitable discretion to modify its injunction based on a claimed public interest in distributing marijuana to those who claim to have a medical need for it.

2. a. The issue of whether the CSA forecloses the availability of a medical necessity defense is one of exceptional and continuing importance. For the first time, a court of appeals has ruled that persons and entities may lawfully engage in the distribution of marijuana if, in their view, the recipients of the marijuana

medically need the drug. That holding flouts the CSA's ban on the distribution of Schedule I controlled substances unless the distributor is registered with the DEA and conducting research approved by the FDA. See 21 U.S.C. 823(f). The court of appeals' decision likewise circumvents the Act's exclusive provisions for drug approval and rescheduling of controlled substances. See 21 U.S.C. 811, 812. And the decision relegates to district courts and juries the power to determine whether illicit drugs can be used safely and effectively as medicine, even though Congress in the CSA placed such determinations within the province of the Attorney General and the Secretary of Health and Human Services. Thus, the Ninth Circuit's decision seriously undermines the administration and effectiveness of the CSA.

The decision is also significant because it threatens the government's ability to enforce the federal drug laws in the nine States within the Ninth Circuit, which comprises a population of nearly 50 million people. U.S. Dep't of Commerce, *Statistical Abstract of the United States* (1994). Indeed, the Ninth Circuit's sanctioning of the distribution of controlled substances in a manner that the CSA expressly prohibits creates incentives for drug manufacturers and distributors involved in a wide variety of offenses involving marijuana (and other Schedule I controlled substances, such as heroin or LSD) to invoke medical necessity as a defense to their alleged drug trafficking. The recognition of such a defense will introduce illegitimate collateral issues into drug prosecutions and will consume unnecessary judicial resources by distracting the trier of fact from the core issues of guilt or innocence of a particular crime as defined by Congress in the CSA.

For example, in a recent case prosecuted in the Eastern District of California, a motions panel of the Ninth Circuit reversed a district court's order denying bail pending appeal, holding that, in view of the Ninth Circuit's decision in this case, the defendant, a distributor of marijuana, was "entitled to bail pending appeal if he can demonstrate: 1) a likelihood that he was entitled to present a medical necessity defense at trial; and 2) his release does not pose a danger that he will distribute marijuana to people not falling within the class of individuals described in *OCBC*." *United States* v. *Smith*, No. 99-10447 (9th Cir. Feb. 3, 2000), slip op. 1-2.

The court of appeals' recognition of a medical necessity defense also takes on added significance in light of the fact that a number of States in the Ninth Circuit—Alaska, California, Hawaii, Oregon, and Washington—have enacted legislation sanctioning the use of marijuana for medicinal purposes. See Alaska Stat. §§ 17.37.010-17.37.080 & 11.71.090 (1999); Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d); Haw. S.B. 862, 20th Legis. (1999) (signed into law on July 12, 2000); Or. Rev. Stat. §§ 475.300-475.346 (1999); Wash. Rev. Code §§ 69.51.010-69.51.080 (1997).[9] In those States, there is therefore no state law that would independently bar

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[9] A medical marijuana ballot measure likewise was approved by voters in Maine in November 1999. Carey Goldberg, *Maine Mulls Medical Use for its Seized Marijuana*, N.Y. Times, Mar. 14, 2000 at Nat'l Desk. We have been informed by the DEA that medical marijuana initiatives are underway in Arizona, Nevada, Colorado, Iowa, Maryland, Massachusetts, Minnesota, New Hampshire, and New York. A majority of voters in the District of Columbia also approved a marijuana initiative in November 1998, but Congress blocked implementation of that initiative. See 145 Cong. Rec. H12,238 (daily ed. Nov. 17, 1999).

the distribution of marijuana in the circumstances that the Ninth Circuit has sanctioned. Thus, unless the CSA can be enforced with respect to that distribution, drug traffickers, acting under the guise of "medical necessity," will be able to manufacture and distribute marijuana with impunity, even though the CSA reflects Congress's deliberate judgment that marijuana shall not be used for medicinal purposes outside the specific confines of the Act itself.

Finally, the Ninth Circuit's decision threatens the government's more general ability to enforce the federal drug laws with respect to other illegal and unapproved drugs. As this Court recognized in *Rutherford*:

> It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked.

442 U.S. at 557-558. That reasoning is equally applicable in this case. Under the Ninth Circuit's analysis, there is no reason that a defendant charged with offenses involving other Schedule I controlled substances or unapproved drugs—such as Laetrile—would not similarly be able to raise the defense of "medical necessity." The Ninth Circuit's decision therefore could significantly undermine the enforcement of the federal drug laws and the FDA drug-approval process, a result patently at odds with the statutory framework

that Congress has enacted. The court of appeals' decision therefore warrants this Court's review.

b. No further proceedings in the lower courts are needed to clarify the issues presented or to render the case suitable for resolution by this Court. As explained above, the Ninth Circuit held: (a) that medical necessity is a "legally cognizable defense" to a marijuana prosecution or a suit for an injunction against marijuana distribution, App. 8a; (b) that OCBC had "identified a strong public interest in the availability of a doctor-prescribed treatment [of marijuana] that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses," *id.* at 9a-10a; and (c) that the government, which had "rel[ied] exclusively on its general interest in enforcing its statutes," had identified no "interest * * * in blocking the distribution of marijuana to those with medical needs," *id.* at 11a. To be sure, the court of appeals did not order the injunction modified to permit the distribution of marijuana, but rather referred the case to the district court for a determination whether the injunction should be modified in that respect. On remand, however, the district court granted OCBC's request to modify the injunction, and did so "in light of the Ninth Circuit's opinion." *Id.* at 13a. Thus, no further factual development is needed for this Court to resolve the legal issues presented.

Moreover, there is no reason to await an appeal of the district court's modification order in order to clarify the question presented. Although the government has filed a notice of appeal from the district court's July 17, 2000, order modifying the injunction, there is no reason to believe that the Ninth Circuit panel, which has retained jurisdiction over any appeal, App. 11a, will revisit its

fundamental holding that medical necessity is a legally cognizable defense that justifies violating the CSA—especially since the Ninth Circuit declined to reconsider that holding on the government's petition for rehearing and rehearing en banc.

Finally, with respect to the circumstances of this case, the court of appeals has already determined that "[t]he evidence in the record is sufficient to justify the requested modification." App. 10a. Indeed, the court of appeals stated that it had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Ibid.* Given the terms of the court of appeals' remand, and the district court's actual modification of the injunction, further proceedings are unlikely to assist this Court in its review of the basic legal issues presented. And at the same time, to postpone review of the Ninth Circuit's holding would only exacerbate its adverse consequences by encouraging broad disregard of the Controlled Substances Act and the unregulated distribution of marijuana, with the attendant serious potential for abuse Congress sought to prevent by placing marijuana in Schedule I under the Act.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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JULY 2000

Supreme Court, U.S.
FILED

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OFFICE OF THE CLERK

No.

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Nos. 98-16950, 98-17044 and 98-17137

UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE;
JEFFREY JONES, DEFENDANTS-APPELLANTS

Appeal from the United States District Court
For the Northern District of California

[Argued and Submitted: April 13, 1999
Decided: Sept. 13, 1999]

Before: SCHROEDER, REINHARDT and SILVERMAN, Circuit Judges.

PER CURIAM:

This interlocutory appeal involves a preliminary injunction entered at the United States' request, to stop the distribution of cannabis in the wake of California's initiative supporting the medical use of marijuana. The district court held that the distribution of marijuana by certain cannabis clubs and their agents, including appellant, Oakland Cannabis Buyers' Cooperative and Jeffrey Jones (collectively "OCBC"), likely violates the

Comprehensive Drug Abuse Prevention and Control Act of 1970 (the "Controlled Substances Act"), 21 U.S.C. § 841(a)(1). *See United States v. Cannabis Cultivators Club*, 5 F.Supp.2d 1086, 1105 (N.D. Cal. 1998). The district court also indicated that it would consider in subsequent contempt proceedings a defense that a particular distribution was justified by a medical necessity. *Id.* at 1102. OCBC did not appeal the district court's order enjoining the distribution of marijuana by cannabis clubs. Instead, OCBC seeks to appeal three subsequent orders: (a) an order denying OCBC's motion to dismiss the complaint on the ground that an Oakland City ordinance makes it immune from liability under 21 U.S.C. § 885(d); (b) an order subsequently purged and vacated that found OCBC in contempt of the injunction; and (c) an order denying OCBC's motion to modify the injunction to permit cannabis distribution to persons having a doctor's certificate that marijuana is a medical necessity for them.

We lack jurisdiction over the appeal from the denial of the motion to dismiss and from the contempt order that has been purged. We have jurisdiction over the appeal from the denial of the motion to modify. We do not vacate the injunction, but remand for the district court to consider modifying the order.

Denial of the Motion to Dismiss

The district court denied the defendants' motion to dismiss that was grounded in the Oakland City Council's attempt to immunize OCBC under the Controlled Substances Act. The district court held that section 885(d) of the Controlled Substances Act is intended to protect state law enforcement officials when they en-

gage in undercover drug operations, and these defendants do not engage in such activities.

We lack jurisdiction of the appeal because the denial of a motion to dismiss is generally not appealable. *See* 28 U.S.C. §§ 1291 & 1292 (granting appellate jurisdiction over final orders and limited interlocutory orders). The denial of the motion to dismiss is not one of the interlocutory orders that can be appealed under § 1292, and it is not a final judgment under § 1291. *See, e.g., Credit Suisse v. United States Dist. Ct.*, 130 F.3d 1342, 1345-46 (9th Cir. 1997).

OCBC contends we have jurisdiction under 28 U.S.C. § 1292(a)(1) authorizing, *inter alia*, appellate jurisdiction over an interlocutory order "continuing . . . or refusing to dissolve or modify injunctions." OCBC asks us to treat the district court's denial of the motion to dismiss as, in effect, a continuance of the injunction and a refusal to dissolve it. OCBC relies upon *Jung Hyun Sook v. Great Pacific Shipping Co.*, 632 F.2d 100, 102 n. 4 (9th Cir. 1980).

The motion to dismiss in *Jung Hyun Sook*, however, was not a motion to dismiss the action in its entirety, but a motion intended specifically to dissolve an injunction. There the district court had enjoined the further prosecution of a Jones Act suit pending the determination of a petition to limit liability. *Id.* at 102. The district court's denial of the motion to dismiss the limitation of liability petition was appealable because its denial continued in effect the injunction against further prosecution of the Jones Act suit. The purpose of the motion to dismiss in that case was not to decide the merits of the litigation, but only to dissolve the injunction. *See* 16 Wright, Miller & Cooper, *Federal Practice*

and Procedure, § 3924.2, at 198-99 n.6 (2d ed. 1996). The motion to dismiss in this case was intended to resolve the entire dispute on the merits. While one effect of granting OCBC's motion to dismiss in this case would have been to dissolve the preliminary injunction, the broader purpose was to resolve the case in defendants' favor. The general rule barring appeals from the denial of motions to dismiss, therefore, must apply. *See Credit Suisse*, 130 F.3d at 1345-46 ("The district court's denial of [defendants'] motion to dismiss is not a 'final decision' within the meaning of 28 U.S.C. § 1291, and it is therefore not immediately reviewable.").

Nor did the district court's denial of the motion to dismiss constitute an order "continuing" the injunction within the meaning of 28 U.S.C. § 1292(a)(1). An order that "continues" an injunction under that statute is an order that extends the duration of the injunction that would otherwise have dissolved by its own terms. *See* 16 Wright, Miller & Cooper, *supra*, at 196; *see also Public Serv. Co. of Colorado v. Batt*, 67 F.3d 234, 236-37 (9th Cir. 1995); *In re Fugazy Express, Inc.*, 982 F.2d 769, 777 (2d Cir. 1992).

OCBC also argues that the denial of the motion to dismiss is appealable as a "collateral order" under the theory of the Supreme Court's decision in *Mitchell v. Forsyth*, 472 U.S. 511, 105 S. Ct. 2806, 86 L.Ed.2d 411 (1985). *Mitchell* permits appeal from orders denying immunity from suit to government officials on damage claims for violations of federal rights. Such orders are immediately reviewable because the immunity at stake is not merely an immunity from liability but an "immunity from suit" that is effectively lost if a case goes to trial. *See id.* at 526, 105 S. Ct. 2806. Section 885(d) is

not such an immunity from suit, but is on its face simply an immunity from liability. It provides that "no civil or criminal liability will be imposed" upon law enforcement officers who engage in drug activity as part of their duties. 21 U.S.C. § 885(d). Thus, OCBC can obtain effective review of its liability (or immunity) under the Controlled Substances Act after the district court has rendered a final judgment.

In addition, the order being appealed is not a "collateral order" involving an important issue separate from the merits of the lawsuit. *See Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546, 69 S. Ct. 1221, 93 L.Ed. 1528 (1949). The merits of the government's suit depend squarely upon whether or not OCBC is immune from liability under § 885(d).

The Contempt Order

OCBC appeals the district court's order finding it in contempt and modifying the preliminary injunction so as to empower the U.S. Marshal to seize OCBC's offices. The court neither fined nor jailed members of OCBC as a result of the contempt. The district court subsequently vacated this modification to the injunction on October 30, 1998 after OCBC told the court that it would comply with the injunction. Consequently, OCBC was permitted to re-enter its offices.

The government argues that this appeal is moot because the modification order was vacated and the contempt purged. "A long line of precedent holds that once a civil contempt order is purged, no live case or controversy remains for adjudication." *Thomassen v. United States*, 835 F.2d 727, 731 (9th Cir. 1987); *accord In re Campbell*, 628 F.2d 1260, 1261 (9th Cir. 1980).

However, a party asserting that an issue is moot must demonstrate that there is no reasonable expectation that the violation will recur. *See County of Los Angeles v. Davis*, 440 U.S. 625, 631, 99 S. Ct. 1379, 59 L.Ed.2d 642 (1979); *Campbell*, 628 F.2d at 1261.

This court has held that a purged contempt order is moot unless there is "near certainty" that the violation will recur. *Campbell*, 628 F.2d at 1262. That is not the case here. In its reply brief, OCBC reiterates that it has promised the district court that it will comply with the injunction. The only way for the violation to recur is if OCBC breaks its promise. Clearly, it is not a "near certainty" that OCBC will do so. Moreover, although the purged contempt order at issue in *Campbell* was not moot, the court explicitly limited its result to the facts of that case: "We emphasize that were it not for the statement of the grand jury foreman [informing the witness that he would be required to testify again in the future], we would be inclined to find that the purging of the contempt orders mooted the present appeals." *Id.* at 1261.

OCBC also contends that the appeal of the contempt order is not moot because it is "capable of repetition, yet evading review." An issue may evade review because of an inherent limit in the duration of a challenged action that prevents full litigation before it ends. *See Phoenix Newspapers, Inc. v. United States Dist. Ct.*, 156 F.3d 940, 945 (9th Cir. 1998). However, nothing inherently limited the duration of OCBC's contempt other than its own decision to purge. The appeal is now moot because OCBC voluntarily purged the contempt by declaring that it would comply with the injunction. Had OCBC chosen to remain in contempt to this day,

the appeal would not be moot because this court could have provided a remedy.

OCBC argues that even if the denial of the motion to dismiss and the modification order are not in and of themselves appealable, the court should assert pendent appellate jurisdiction because they are "inextricably intertwined" with the denial of the motion to modify the injunction, which is appealable. *See Swint v. Chambers County Comm'n*, 514 U.S. 35, 51, 115 S. Ct. 1203, 131 L.Ed.2d 60 (1995). We have held that the "inextricably intertwined" doctrine should be narrowly construed; more is required than that separate issues rest on common facts. *See California v. Campbell*, 138 F.3d 772, 778 (9th Cir.), *cert. denied*, 525 U.S. 822, 119 S. Ct. 64, 142 L.Ed.2d 51 (1998). The legal theories on which the motion to dismiss, the contempt order, and the motion to modify are independent of each other. Each required application of different legal principles. They are not therefore so "intertwined" as to necessitate simultaneous review.

Denial of the Motion to Modify

OCBC contends that the district court abused its discretion by refusing to modify its injunction to permit cannabis distribution to patients for whom it is a medical necessity. A few days after the district court issued its contempt citation instructing the Marshals to padlock its premises, OCBC asked the district judge to modify the injunction to allow continuing cannabis distribution to patients whose physicians certify that (1) the patient suffers from a serious medical condition; (2) if the patient does not have access to cannabis, the patient will suffer imminent harm; (3) cannabis is necessary for the treatment of the patient's medical con-

dition or cannabis will alleviate the medical condition or symptoms associated with it; (4) there is no legal alternative to cannabis for the effective treatment of the patient's medical condition because the patient has tried other legal alternatives to cannabis and has found them ineffective in treating his or her condition or has found that such alternatives result in intolerable side effects. These factors were modeled on this court's recognition of a necessity defense to violations of federal law in *United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir. 1989).

The denial of a motion to modify an injunction is independently appealable under § 1292(a)(1) as one of the appealable interlocutory orders denominated in that section. Therefore, we have jurisdiction to review the order denying OCBC's motion for modification.

The district court summarily denied OCBC's motion, saying that it lacked the power to make the requested modification because "its equitable powers do not permit it to ignore federal law." In doing so, the district court misapprehended the issue. The court was not being asked to ignore the law. It was being asked to take into account a legally cognizable defense that likely would pertain in the circumstances.

The government did not need to get an injunction to enforce the federal marijuana laws. If it wanted to, it could have proceeded in the usual way, by arresting and prosecuting those it believed had committed a crime. Had the government proceeded in that fashion, the defendants would have been able to litigate their necessity defense under *Aguilar* in due course. However, since the government chose to deal with potential violations on an anticipatory basis instead of prosecut-

ing them afterward, the government invited an inquiry into whether the injunction should *also* anticipate likely exceptions. This gives rise to a drafting issue—crafting an injunction that is broad enough to prohibit illegal conduct, but narrow enough to exclude conduct that likely would be legally privileged or justified.

In *Northern Cheyenne Tribe v. Hodel*, we held that courts retain broad equitable discretion when it comes to injunctions against violations of federal statutes unless Congress has clearly and explicitly demonstrated that it has balanced the equities and mandated an injunction. 851 F.2d 1152, 1156 (9th Cir. 1988). Here, although the government may be entitled to its requested injunction, there is no evidence that Congress intended to divest the district court of its broad equitable discretion to formulate appropriate relief when and if injunctions are sought. Further, there is no indication that the "underlying substantive policy" of the Act mandates a limitation on the district court's equitable powers. *Id.* at 1156.

The district court erred in another respect as well. In deciding whether to issue an injunction in which the public interest would be affected, or whether to modify such an injunction once issued, a district court must expressly consider the public interest on the record. The failure to do so constitutes an abuse of discretion. *Northern Cheyenne Tribe*, 851 F.2d at 1156; *American Motorcyclist Association v. Watt*, 714 F.2d 962, 965 (9th Cir. 1983); *Caribbean Marine Serv. Co. v. Baldrige*, 844 F.2d 668, 678 (9th Cir. 1988). OCBC has identified a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the

condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses. Indeed, the City of Oakland has declared a public health emergency in response to the district court's refusal to grant the modification under appeal here. Materials submitted in support of OCBC's motion to modify the injunction show that the proposed amendment to the injunction clearly related to a matter affecting the public interest. Because the district court believed that it had no discretion to issue an injunction that was more limited in scope than the Controlled Substances Act itself, it summarily denied the requested modification without weighing or considering the public interest.

We have no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion. The evidence in the record is sufficient to justify the requested modification. OCBC submitted the declarations of many seriously ill individuals and their doctors who, despite their very real fears of criminal prosecution, came forward and attested to the need for cannabis in order to treat the debilitating and life threatening conditions.

In short, OCBC presented evidence that there is a class of people with serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects.

The government, by contrast, has yet to identify any interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes. It has offered *no* evidence to rebut OCBC's evidence that cannabis is the only effective treatment for a large group of seriously ill individuals, and it confirmed at oral argument that it sees no need to offer any. It simply rests on the erroneous argument that the district judge was compelled as a matter of law to issue an injunction that is coextensive with the facial scope of the statute.

The district court, accepting the government's argument that it lacked the authority to grant the requested modification, failed to undertake the required analysis and summarily denied OCBC's request. Accordingly, we reverse the order denying the modification and remand. On remand, the district court is instructed to reconsider the appellants' request for a modification that would exempt from the injunction distribution to seriously ill individuals who need cannabis for medical purposes. In particular, the district court is instructed to consider, in light of our decision in *United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir. 1989), the criteria for a medical necessity exemption, and, should it modify the injunction, to set forth those criteria in the modification order.

The panel will retain jurisdiction over any further appeals in this case.

The case is REMANDED for further proceedings consistent with this opinion.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL.,
DEFENDANTS

[Filed: July 17, 2000]

ORDER

Now before the Court is defendants' motion to modify the injunction issued on May 19, 1998, or in the alternative, to dissolve the injunction. After carefully considering the papers filed by the parties, and having had the benefit of oral argument, the motion to modify the injunction is GRANTED.

In *United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109 (9th Cir. 1999), the Ninth Circuit reversed the Court's order denying defendants' motion to modify the injunction and instructed the Court "to reconsider the [defendants'] request for a modification that would exempt from the injunction distribution to seriously ill individuals who need cannabis for medical purposes." *Id.* at 1115. In doing so, the court held that this Court must consider the public interest, and that

the evidence in the record "show[s] that the proposed amendment to the injunction clearly related to a matter affecting the public interest." *Id.* at 1114. Significantly, the Ninth Circuit also held that the government had not "identif[ied] any interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes." *Id.* The court noted that the government "has offered *no* evidence to rebut OCBC's evidence that cannabis is the only effective treatment for a large group of seriously ill individuals." *Id.*

On remand the government has still not offered any evidence to rebut defendants' evidence that cannabis is medically necessary for a group of seriously ill individuals. Instead, the government continues to press arguments which the Ninth Circuit rejected, including the argument that the Court must find that enjoining the distribution of cannabis to seriously ill individuals is in the public interest because Congress has prohibited such conduct in favor of the administrative process regulating the approval and distribution of drugs. As a result of the government's failure to offer any new evidence in opposition to defendants' motion, and in light of the Ninth Circuit's opinion, the Court must conclude that modifying the injunction as requested is in the public interest and exercise its equitable discretion to do so.

Accordingly, the injunction issued on May 19, 1998 will be modified as follows:

> The foregoing injunction does not apply to the distribution of cannabis by the Oakland Cannabis Buyers' Cooperative and Jeffrey Jones to patient-members who (1) suffer from a serious medical

condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's legal medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or alleviating the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

The Court DENIES defendants' motion to dissolve the injunction. Nothing in the Ninth Circuit's decision suggests that the Court should dissolve the injunction, especially in light of the above modification.

IT IS SO ORDERED.

Dated: July 17, 2000

/s/ CHARLES R. BREYER
CHARLES R. BREYER
United States District Judge

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-0088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL.,
DEFENDANTS

[Filed: July 17, 2000]

AMENDED PRELIMINARY INJUNCTION ORDER

For the reasons stated in its Memorandum and Order dated May 13, 1998 and its Order dated July 17, 2000, it is hereby ORDERED as follows:

1. Defendants Oakland Cannabis Buyers' Cooperative and Jeffrey Jones are hereby preliminarily enjoined, pending further order of the Court, from engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana, in violation of 21 U.S.C. § 841(a)(1); and

2. Defendants Oakland Cannabis Buyers' Cooperative and Jeffrey Jones are hereby preliminarily enjoined from using the premises of 1755 Broadway, Oak-

land, California for the purposes of engaging in the manufacture and distribution of marijuana; and

3. Defendant Jeffrey Jones is hereby preliminarily enjoined from conspiring to violate the Controlled Substances Act, 21 U.S.C. § 841(a)(1) with respect to the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana.

4. It shall not be a violation of this injunction for defendants to seek and obtain legal advice from their attorneys.

5. Pursuant to Federal Rule of Civil Procedure 65(d), this injunction shall bind the defendants, their officers, agents, servants, employees, successors, and attorneys, and upon those persons in active concert or participation with them who receive notice of the order by personal service or otherwise.

6. The foregoing injunction does not apply to the distribution of cannabis by the Oakland Cannabis Buyers' Cooperative and Jeffrey Jones to patient-members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or allevia-

ting the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

IT IS SO ORDERED.

Dated: July 17, 2000

/s/ CHARLES R. BREYER
CHARLES R. BREYER
United States District Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB, C 98-00086 CRB,
C 98-00087 CRB, C 98-00088 CRB,
C 98-00245 CRB.

UNITED STATES, PLAINTIFF

v.

CANNABIS CULTIVATORS CLUB, ET AL., DEFENDANTS

AND RELATED CASES

[Filed: Oct. 16, 1998]

ORDER IN CASE NO. 98-00088
(OAKLAND CANNABIS BUYERS' COOPERATIVE)

On October 13, 1998, the Court issued a Memorandum and Order modifying the preliminary injunction order issued on May 19, 1998 ("the October 13th Order"). The Court stayed the October 13th Order until 5:00 p.m. today. Now before the Court is defendants' ex parte application for a further stay pend-

ing appeal and for modification of the preliminary injunction order.

Good cause appearing therefore, defendants' request that the Court continue the stay of the October 13, 1998 Order to permit defendants to file an emergency request for a stay in the Ninth Circuit Court of Appeals is GRANTED. The Court hereby STAYS the October 13th Order until 5:00 p.m. Monday, October 19, 1998, *provided defendants file their request for an emergency stay with the Ninth Circuit Court of Appeals by the close of business today*, Friday, October 16, 1998. All further requests for a stay must be directed to the Ninth Circuit Court of Appeals.

Defendants' request for a stay pending resolution of their appeal is DENIED. Defendants' request to modify the preliminary injunction is also DENIED.

IT IS SO ORDERED.

Dated: October 16, 1998

/s/ CHARLES R. BREYER
CHARLES R. BREYER
United States District Judge

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB, C 98-00086 CRB,
C 98-00087 CRB, C 98-00088 CRB,
C 98-00245 CRB

UNITED STATES, PLAINTIFF

v.

CANNABIS CULTIVATORS CLUB, ET AL., DEFENDANTS

AND RELATED CASES

[Filed: Oct. 13, 1998]

MEMORANDUM AND ORDER RE: MOTIONS IN LIMINE AND ORDER TO SHOW CAUSE IN CASE NO. 98-00088 (Oakland Cannabis Buyers' Cooperative)

Now before the Court are plaintiff's motions in limine to exclude defendants' affirmative defenses and the Court's Order to Show Cause why defendants are not in contempt of the Court's May 19, 1998 order. After carefully considering the papers and evidence sub-

mitted by the parties, and having had the benefit of oral argument on October 5, 1998, plaintiff's motions are GRANTED. The Court further finds that defendants have not offered any evidence to controvert plaintiff's evidence that defendants' violated the May 19, 1998 preliminary injunction order. Thus, defendants are in contempt of the injunction.

BACKGROUND

On May 19, 1998, the Court issued an order preliminarily enjoining defendants Oakland Cannabis Buyers' Cooperative ("OCBC") and Jeffrey Jones, from, among other things, "engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture or distribute marijuana, in violation of 21 U.S.C. § 841(a)(1)," and "using the premises of 1755 Broadway, Oakland, California for the purposes of engaging in the manufacture and distribution of marijuana." Upon motion of the plaintiff, and after hearing oral argument and considering the papers submitted by the parties, the Court ordered defendants to show cause "why they should not be held in civil contempt of the Court's May 19, 1998 Preliminary Injunction Order by distributing marijuana and by using the premises of 1755 Broadway, Oakland, California, for the purpose of distributing marijuana, on May 27, 1998." The show cause order was based upon evidence submitted by plaintiff as follows:

(1) On May 20, 1998, one day after the Court entered the injunction, defendants OCBC and Jeffrey Jones issued a press release entitled "Oakland Cooperative to Openly Dispense Medical Marijuana for First Time Since Preliminary Injunction – U.S.

Attorney to be Notified: HIV, Multiple Sclerosis and Other Seriously Ill Patients to Receive Pot at 11:00 a.m., Thursday May 21, Oakland Buyers Cannabis Co-operative, 1755 Broadway, Oakland."

(2) A declaration from Special Agent Peter Ott that on May 21, 1998, he entered the OCBC in an undercover capacity and observed approximately fourteen sales or distributions of what appeared to be marijuana by persons associated with the OCBC, including Jeffrey Jones, several of which were made in front of news cameras.

(3) Evidence that the World Wide Web site of the OCBC, which indicates that it was updated on June 1 and August 12, 1998, states: "Currently, we are providing medical cannabis and other services to over 1,300 members."

(4) A declaration from Special Agent Bill Nyfeler that on May 27, 1998 he placed a recorded telephone call to the OCBC, at (510) 832-5346. The individual who answered the phone informed Special Agent Nyfeler that the OCBC was still open for business, and told Special Agent Nyfeler the club's business hours.

(5) A declaration from Special Agent Dean Arnold that on June 16, 1998 he placed a recorded telephone call to the OCBC, at (510) 843-5346. An unidentified male answered the telephone and informed Special Agent Arnold that the OCBC was open for business and was accepting new members. The unidentified male further informed Special Agent Arnold about the requirements of becoming an OCBC member, the hours that the club was open (11 a.m. - 1 p.m., and 5 p.m. - 7

p.m.), and the location of the OCBC, at 1755 Broadway Avenue, in Oakland.

(6) Evidence that in an article entitled *Marijuana Clubs Defy Judge's Order* by Karyn Hunt, which appeared on May 22, 1998, in *AP Online*, defendant Jeffrey Jones is quoted as stating, "We are not closing down. We feel what we are doing is legal and a medical necessity and we're going to take it to a jury to prove that."

The Court's show cause order specifically advised defendants that their response to the order should include sworn declarations outlining the factual basis for any affirmative defenses which they wish to offer.

In response to the show cause order, defendants argue (1) that plaintiff has not made a prima facie showing that defendants violated the Court's injunction, and (2) in the alternative, that defendants have submitted evidence sufficient to support their affirmative defenses of "joint user," "necessity," and "substantive due process." Defendants incorporate all declarations previously filed in this case, and have submitted 12 new declarations, including declarations from eight OCBC patients. The patients testify as to their need for marijuana to alleviate the symptoms of their serious illnesses or disabilities. Of the eight patients, none states that he or she received marijuana from defendants on May 21, 1998, although four, Michael M. Alcalay, M.D., M.P.H., Albert Dunham, Kenneth Estes, and Yvonne Westbrook attest that they were present at the OCBC on that date. The other four do not declare that they were present at the OCBC on May 21.

Several of the declarants, including Dr. Alcalay, the OCBC Medical Director, Laura A. Galli, R.N., an OCBC patient and volunteer nurse, and James D. McClelland, the OCBC Chief Financial Officer and an OCBC board member, testify as to the OCBC's strict requirements for admission to the OCBC. In addition, defendants offer the expert testimony of Harvard physician Lester Grinspoon, M.D. and John P. Morgan, M.D., Professor of Pharmacology at City University of New York as to the medical benefits of marijuana and why other drugs, such as Marinol, are not a reasonable alternative for some patients. At defendants' request, the Court also takes judicial notice of the physician declarations filed in *Conant v. McCaffrey*, 97-0139 FMS.

Plaintiff has moved in limine to exclude defendants' affirmative defenses and defendants have moved for an order granting use immunity to defendants Jeffrey Jones and other witnesses who are unwilling to testify in this action without such immunity. The Court heard oral argument on October 5, 1998, and thereafter took the matter under submission.

DISCUSSION

I. THE MOTIONS FOR IMMUNITY.

District courts generally do not have the authority to confer use immunity for defense witnesses who invoke the Fifth Amendment privilege against self-incrimination. *See United States v. Baker*, 10 F.3d 1374, 1414 (9th Cir. 1993). In *Simmons v. United States*, 390 U.S. 377 (1968), however, the Supreme Court held that "when a defendant testifies in support of a motion to suppress evidence on Fourth Amendment grounds, his

testimony may not thereafter be admitted against him at trial on the issue of guilt unless he makes no objection." *Id.* at 394 ("we find it unconscionable that one constitutional right should have to be surrendered in order to assert another"). The Third Circuit subsequently extended *Simmons* to a criminal defendant confronted with the dilemma of whether to offer favorable testimony at his bail hearing, which testimony was required because of a presumption of dangerousness arising under the Bail Reform Act, or safeguard his Fifth Amendment right not to testify. *See United States v. Perry*, 788 F.2d 100, 115-16 (3d Cir. 1986). The *Perry* court held that the trial court should have granted the defendant use immunity because the defendant's testimony at the bail hearing was "necessary to vindicate the most fundamental of all constitutional rights, the right of liberty from civil incarceration." *Id.* at 116.

Defendant Jones argues that he, too, is being forced to choose between his Fifth Amendment privilege and his right of liberty since he might be fined or even jailed as a sanction if he is found in contempt. Plaintiff, however, has represented that it is not seeking fines or incarceration to compel Jones to comply with the Court's injunction and the Court will not consider such remedies. As Jones is not being forced to choose between competing constitutional rights, *Simmons* and *Perry* are inapplicable even assuming they apply to defendants in a civil contempt proceeding.

Defendants also argue that the Court can and should grant use immunity to defendants' witnesses to protect defendants' right to due process and a fair trial. In *United States v. Lord*, 711 F.2d 887, 890-92 (9th Cir.

1983), and *United States v. Westerdahl*, 945 F.2d 1083, 1085-87 (9th Cir. 1991), the Ninth Circuit recognized that a defendant may be denied a fair trial as a result of the government's failure to provide use immunity to the testimony of a defense witness. *Lord* and *Westerdahl* are inapplicable to these contempt proceedings for two reasons.

First, both cases were criminal prosecutions where the defendant's right to liberty was at stake. Defendants have not cited any cases, and the Court is aware of none, in which the *Lord* and *Westerdahl* principle has been extended to civil cases.

Second, the Ninth Circuit requires some prima facie evidence of prosecutorial misconduct before a grant of immunity may be given. *See Baker*, 10 F.3d at 1414; *Westerdahl*, 945 F.2d at 1086; *Lord*, 711 F.2d at 892. In *Westerdahl*, for example, the government had granted immunity to a key prosecution witness, but had refused to immunize defendant's potentially exculpatory witness. The court held that the district court should have held an evidentiary hearing to determine if the government "intentionally distorted the facts." *Id.* at 1087. Defendants have not made such a prima facie showing here. At best, all that defendants have shown is that plaintiff has refused to immunize defendants' witnesses, forcing the witnesses to decide whether to testify in the contempt proceeding or potentially incriminate themselves. Such a choice cannot in and of itself constitute misconduct since a defendant "has no absolute right not to be forced to choose between testifying in a civil matter and asserting his Fifth Amendment privilege." *Keating v. Office of Thrift Supervision*, 45 F.3d 322, 326 (9th Cir. 1995).

II. THE MOTIONS IN LIMINE.

A. The Legal Standard.

A defendant is entitled to have the judge instruct the jury on his theory of defense only if it is "'supported by law and has some foundation in evidence.'" *United States v. Gomez-Osorio*, 957 F.2d 636, 642 (9th Cir. 1992). A district judge may preclude a party from offering evidence in support of a defense, including a necessity defense, by granting a motion in limine. *See United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir. 1989); *United States v. Dorrell*, 758 F.2d 427, 430 (9th Cir. 1985). "The sole question presented in such situations is whether the evidence, as described in the offer of proof, is insufficient as a matter of law to support the proffered defense." *Dorrell*, 758 F.2d at 430. "If it is, then the trial court should exclude the defense and the evidence offered in support." *Id.*

B. The "Joint User" Defense.

In *United States v. Swiderski*, 548 F.2d 445 (2nd Cir. 1977), defendants, husband and wife, were charged with violating 21 U.S.C. § 841(a) by possessing cocaine with intent to distribute. *See id.* at 447. The Second Circuit held that "a statutory 'transfer' could not occur between two individuals in joint possession of a controlled substance simultaneously acquired for their own use." *United States v. Wright*, 593 F.2d 105, 107 (9th Cir. 1979) (discussing *Swiderski*). The court thus concluded that the trial judge erred by denying "the jury the opportunity to find that the defendants, who bought the drugs in each other's physical presence, intended

merely to share the drugs" and thus, not to distribute them. *Id.*; *Swiderski*, 548 F.2d at 450.

Defendants here, unlike the defendants in *Swiderski*, have not offered any evidence of the literal joint purchase of the marijuana they are alleged to have distributed on May 27, 1998. Defendants contend nonetheless that because the OCBC is operated as a cooperative, the marijuana is effectively purchased together by all its members and is consumed together by all its members since the marijuana is only distributed to members of the cooperative. Thus, defendants argue, they are entitled to a *Swiderski* instruction.

The Court declines to extend *Swiderski* to the facts as presented by defendants' proffer, namely a medical marijuana cooperative. As the Court has previously noted, *Swiderski* involved a simultaneous purchase by a husband and wife who testified they intended to use the controlled substance immediately. Applying *Swiderski* to a medical marijuana cooperative would extend *Swiderski* to a situation in which the controlled substance is not literally purchased simultaneously for immediate consumption. *See United States v. Cannabis Cultivators Club*, 5 F.Supp.2d 1086, 1101 (N.D. Cal. 1998). In light of the fact that *Swiderski* has never been so extended, and in light of the fact that is has not been adopted by the Ninth Circuit, the Court concludes that such a defense is not available on the facts proffered by defendants as a matter of law.

C. <u>The Necessity Defense.</u>

To be entitled to a jury instruction on the defense of necessity, defendants must offer evidence (1) that they

were faced with a choice of evils and chose the lesser evil; (2) they acted to prevent imminent harm; (3) they reasonably anticipated a direct causal relationship between their conduct and the harm to be averted; and (4) that there were no legal alternatives to violating the law. *See United States v. Aguilar*, 883 F.2d 662, 693 (9th Cir. 1989). Defendants have produced evidence that marijuana has a medical benefit to many persons and that for some persons marijuana is the only drug that can alleviate their pain and other debilitating symptoms. They also have submitted evidence that they carefully screen their members to ensure that they have a physician's recommendation for marijuana use. Further, the Court will assume, without deciding, that the four OCBC patients who have submitted declarations and admit to having been present at the OCBC on May 21, 1998, have submitted sufficient evidence as to their need for marijuana to permit a trier of fact to determine if they have a legal necessity for marijuana.

Plaintiff argues that a necessity defense based upon a medical need for marijuana is never available under any circumstances as a defense to a violation of the Controlled Substances Act because Congress implicitly rejected such a defense by placing marijuana in Schedule I. The Court need not address this issue, however, because it concludes that defendants have not produced sufficient evidence in their offer of proof to permit a defense of necessity to the charge that they violated the injunction.

In *Aguilar*, the Ninth Circuit considered a necessity defense offer of proof similar to that offered by defendants here. The *Aguilar* defendants were charged with violations of the immigration laws, arising from

their providing sanctuary to Central American refugees. With respect to the specificity required of a necessity offer of proof, the court held:

> We also doubt the sufficiency of the proffer to establish imminent harm. *The offer fails to specify that the particular aliens assisted were in danger of imminent harm.* Instead, it refers to general atrocities committed by Salvadoran, Guatemalan, and Mexican authorities. The only indication that appellants intended to show that the aliens involved in this action faced imminent harm was their proffer that they adopted a process to screen aliens in order to assure themselves that those helped actually were in danger. *This allegation fails for lack of specificity.*

Id. at 692 n.28 (emphasis added). Defendants' proffer here likewise fails to identify evidence that demonstrates that each of the particular persons to whom they distributed marijuana on May 21, 1998 was in danger of imminent harm.

Plaintiff has submitted the declaration of a Special Agent Ott who testifies that he personally witnessed fourteen marijuana transactions on May 21, 1998. Moreover, defendants' evidence suggests that they may have distributed marijuana to as many as 191 "visitors" to the OCBC on May 21, 1998. Defendants, however, have proffered evidence as to only four patients who admit to visiting the OCBC on May 21. Assuming that these four patients obtained marijuana from the OCBC on May 21, defendants have, at best, offered a necessity defense to only four of the fourteen transactions identified by plaintiff, putting aside the fact that defendants' own evidence suggests there were as many as 191

marijuana transactions that day. Such a proffer does not meet the specificity requirements of *Aguilar*, namely, that defendants proffer evidence that the particular persons to whom they distributed marijuana were as a matter of fact in danger of imminent harm. As the Court stated before the injunction was issued, "for the defense of necessity to be available here, *defendants would have to prove that each and every patient* to whom it provides cannabis is in danger in imminent harm; that the cannabis will alleviate the harm for that particular patient; and that the patient had no other alternatives, for example, that no other legal drug could have reasonably averted the harm." *Cannabis Cultivators Club*, 5 F. Supp.2d at 1102 (emphasis added). Defendants have not done so in response to the show cause order, and they have not offered that they could do so at a jury trial.

Moreover, under *Aguilar*, defendants' evidence as to the OCBC's stringent admission requirements and their evidence as to the medical benefits of marijuana generally, rather than to the particular persons to whom defendants distributed marijuana on May 21, is immaterial as a matter of law. The defendants must show that *each* person to whom they distributed marijuana was actually in danger of imminent harm. It is not sufficient that defendants reasonably believed each person to be in such danger.

Defendants contend that a jury should be allowed to consider their necessity defense because their evidence demonstrates that on May 21, 1998 they were in substantial compliance with the Court's injunction. Under defendants' reasoning, however, a defendant would be excused from complying with the Controlled Sub-

stances Act because *some*, but not all, of the people to whom they distributed marijuana had a legal necessity. No case of which this Court is aware has ever allowed such a blanket exemption to the criminal laws.

Defendants argue in the alternative that their proffer could not be more specific because plaintiff failed to identify the specific persons to whom plaintiff alleges defendants distributed marijuana. The Order to Show Cause, however, was limited to a single day and the plaintiff's evidence as to the government agent's personal observation of fourteen marijuana transactions in the OCBC—transactions which the defendants announced publicly in advance and invited the public, including the United States Attorney for the Northern District of California, to witness—occurred during a fifteen to twenty minute period. Plaintiff's evidence thus places particular transactions at issue. If defendants did not distribute marijuana on May 21, 1998, they could offer evidence that they did not. If they did distribute marijuana that day, such distribution violated the injunction. *See Cannabis Cultivators Club*, 5 F. Supp.2d at 1100 (holding that the Controlled Substances Act "does not exempt the distribution of marijuana to seriously ill persons for their personal medical use"). If they believe their violations of the injunction are excused by the defense of necessity, it is incumbent upon defendants to come forward with the evidence to support their defense as to each violation. They have not done so for all, or even most, of the transactions at issue. Accordingly, their defense of necessity fails as a matter of law.

D. **Substantive Due Process.**

Defendants contend that they are not in contempt because the OCBC members have a fundamental right to "a demonstrated and effective treatment as recommended by their physician that can alleviate their agony, preserve their sight, and save their lives." Assuming, without deciding, that such a fundamental right exists, the defense fails for the same reason their necessity defense fails; defendants have failed to proffer evidence that each and every person to whom they distributed marijuana needed the marijuana to protect such a fundamental right. *See Cannabis Cultivators Club*, 5 F. Supp.2d at 1103. To hold otherwise would mean that because defendants have a substantive due process defense to some of the marijuana distributions in which they engaged, they are excused from all of their violations of the injunction. Defendants have not cited any case law or legal principles that would permit such an exemption from the federal laws.

II. **THE CONTEMPT PROCEEDINGS.**

A. **Whether Defendants Are In Contempt.**

The Court preliminarily enjoined defendants from violating the Controlled Substances Act pursuant to 21 U.S.C. section 882(a). As this Court has previously noted, 21 U.S.C. section 882(b) provides that "[i]n case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by jury in accordance with the Federal Rules of Civil Procedure." The plaintiff nonetheless argues that the Court should find defendants in

contempt without a jury trial because plaintiff's evidence of defendants' violation of the Court's injunction is uncontroverted.

In the Ninth Circuit, a civil contempt proceeding is a trial within the meaning of Federal Rule of Civil Procedure 43(a), rather than a hearing on a motion within the meaning of Rule 43(e). *See Hoffman v. Beer Drivers and Salesmen's Local Union No. 888*, 536 F.2d 1268, 1277 (9th Cir. 1976). A trial with live testimony, however, is not always required before contempt sanctions may be issued. In *Peterson v. Highland Music, Inc.*, 140 F.3d 1313 (9th Cir. 1998), *cert. pet. filed* Sep. 14, 1998, for example, the district court commenced contempt proceedings by issuing an order to show cause. The court then had the parties file affidavits and extensively brief the relevant issues. The court did not, however, hold an evidentiary hearing (or trial) with live testimony. Instead, the district court issued its contempt sanctions at the end of the hearing on the order to show cause. *See id.* at 1324.

The Ninth Circuit affirmed the imposition of the contempt sanctions. The court held that while "ordinarily" a court should not impose contempt sanctions on the basis of affidavits, "'[a] trial court may in a contempt proceeding narrow the issues by requiring that affidavits on file by controverted by counter-affidavits and may thereafter treat as true the facts set forth in uncontroverted affidavits.'" *Id.* (quoting *Hoffman*, 536 F.2d at 1277). The court concluded that such procedures do not violate due process.

Defendants contend that the Court must grant them a jury trial on the issue of contempt because "[f]act-

finding is usually a function of the jury, and the trial court rarely rules on a defense as a matter of law." *United States v. Contento-Pachon*, 723 F.2d 691, 693 (9th Cir. 1984). Defendants also urge that a court should exclude evidence of a defense only if the evidence is insufficient as a matter of law to support the defense. *See id.* The Court agrees. Here, however, the Court has ruled that the evidence submitted by defendants is insufficient as a matter of law to support the defenses of "joint user," "necessity," and "substantive due process." The question presented is thus whether there are any "facts" for a jury to decide. Defendants have offered no facts whatsoever to controvert plaintiff's evidence that defendants distributed marijuana at the OCBC on May 21, 1998. Nor have they identified any evidence that they could present to a jury that they have not already presented that would create a dispute of fact. *If there are no facts to be decided by a jury, there is no reason to have a jury trial.*

The Court has reviewed the statute conferring the right to a jury trial and concludes that its decision that defendants are entitled to a jury trial only if there is a material dispute of fact is not inconsistent with the statute. Congress provided defendants with a right to a jury trial "in accordance with the Federal Rules of Civil Procedure." 21 U.S.C. § 882(b). Thus, this is not a criminal proceeding in which a defendant is entitled to a jury trial even if there are no disputes of fact. *Compare* 21 U.S.C. § 882(b) *with* 18 U.S.C. § 3691 ("Whenever a contempt charged shall consist in willful disobedience of any lawful writ, process, order, rule, decree, or command of any district court of the United States by doing or omitting any act or thing in violation thereof, and the act or thing done or omitted also constitutes a criminal

offense under any Act of Congress, or under the laws of any state in which it was done or omitted, *the accused, upon demand therefor, shall be entitled to trial by a jury, which shall conform as near as may be to the practice in other criminal cases*") (emphasis added). Moreover, since the trial is to be conducted in accordance with the Rules of Civil Procedure, Rule 50 with respect to "Judgment as a Matter of Law" applies. If the question of whether defendants violated the Court's order on May 21, 1998 were tried to a jury, the Court would be obligated to grant judgment in accordance with Rule 50 since there is no dispute that defendants violated the injunction and the Court has concluded that defendants do not have a defense to their violations as a matter of law.

Defendants also argue that plaintiff's evidence is insufficient to support a finding of contempt by clear and convincing evidence, even without considering defendants' affirmative defenses. The Court disagrees. Plaintiff submitted uncontroverted evidence that defendants issued a press release announcing that they were going to distribute marijuana at the OCBC on May 21, 1998. Plaintiffs also produced uncontroverted evidence that a government agent visited the OCBC at the time defendants announced they were going to distribute marijuana and that the agent personally witnessed fourteen marijuana transactions. This uncontroverted evidence is clear and convincing evidence that defendants violated the injunction and thus are in contempt of May 19, 1998 order.

B. The Remedy For Defendants' Contempt.

Plaintiff asks the Court to compel defendants to comply with the injunction by modifying the May 19, 1998 order to empower the United States Marshal to enforce the injunction. Plaintiff does not ask the Court to fine defendants or to incarcerate defendant Jeffrey Jones to compel compliance and the Court will not do so. The Court concludes that the remedy proposed by plaintiff is reasonable and designed to enforce compliance.

The Court understands defendants' argument that in this action the Court is sitting in equity and therefore must consider the human suffering that will be caused by plaintiff's success in closing down the OCBC. While the Court is sitting in equity, however, its equitable powers to not permit it to ignore federal law. Federal law prohibits the distribution of marijuana to seriously ill persons for their personal medical use. *See Cannabis Cultivators Club*, 5 F. Supp.2d at 1100. The Court accordingly proposes to modify its May 19, 1998 preliminary injunction in 98-00088 to provide as follows:

> The United States Marshal is empowered to enforce this Preliminary Injunction. In particular, the United States Marshal is authorized to enter the premises of the Oakland Cannabis Buyers' Cooperative at 1755 Broadway, Oakland, California, at any time of the day or night, evict any and all tenants, inventory the premises, and padlock the doors, until such time that defendants can satisfy the Court that they are no longer in violation of the injunctive order and that they would in good faith thereafter comply with the terms of the order.

The Court will stay the imposition of the modification to the injunction until 5:00 p.m. on Friday, October 16, 1998 to give defendants the opportunity to seek interim appellate relief.

CONCLUSION

For the foregoing reasons, plaintiff's motions to preclude defendants' affirmative defenses of "joint user," "necessity," and "substantive due process," are GRANTED. The Court concludes further that defendants have not offered any evidence to controvert plaintiff's evidence that defendants' [*sic*] distributed marijuana at the OCBC on May 21, 1998 in violation of the Court's May 19, 1998 preliminary injunction order and therefore that there are no factual disputes to be tried to a jury. The Court accordingly finds defendants in contempt of its May 19, 1998 order. In order to compel defendants to comply with the injunction, the Court will modify the injunction to empower the United States Marshal to enforce the injunction order.

IT IS SO ORDERED.

Dated: October 13, 1998

/s/ CHARLES R. BREYER
CHARLES R. BREYER
United States District Judge

APPENDIX F

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNIBAS [*sic*] BUYERS' COOPERATIVE AND JEFFREY JONES, DEFENDANTS

[Filed: May 19, 1998]

PRELIMINARY INJUNCTION ORDER

For the reasons stated in its Memorandum and Order dated May 13, 1998, it is hereby ORDERED as follows:

1. Defendants Oakland Cannibas [*sic*] Buyers' Cooperative and Jeffrey Jones are hereby preliminarily enjoined, pending further order of the Court, from engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana, in violation of 21 U.S.C. § 841(a)(1); and

2. Defendants Oakland Cannibas [*sic*] Buyers' Cooperation and Jeffrey Jones are hereby preliminarily enjoined from using the premises at 1755 Broadway,

Oakland, California for the purposes of engaging in the manufacture and distribution of marijuana; and

3. Defendant Jeffrey Jones is hereby preliminarily enjoined from conspiring to violate the Controlled Substances Act, 21 U.S.C. § 841(a)(1) with respect to the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana.

4. It shall not be a violation of this injunction for defendants to seek and obtain legal advice from their attorneys.

5. Pursuant to Federal Rule of Civil Procedure 65(d), this injunction shall bind the defendants, their officers, agents, servants, employees, successors, and attorneys, and those persons in active concert or participation with them who receive notice of the order by personal service or otherwise.

IT IS SO ORDERED.

Dated: May 19, 1998

/s/ CHARLES R. BREYER
CHARLES R. BREYER
United States District Judge

APPENDIX G

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

Nos. C 98-0085 CRB, C 98-0086 CRB,
C 98-0087 CRB, C 98-0088 CRB,
C 98-0089 CRB and C 98-0245 CRB.

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATORS CLUB; AND
DENNIS PERON, DEFENDANTS
AND RELATED ACTIONS

[Filed: May 13, 1998]

MEMORANDUM AND ORDER

BREYER, District Judge.

INTRODUCTION

The issue presented by these related lawsuits is whether defendants' admitted distribution of marijuana for use by seriously ill persons upon a physician's recommendation violates federal law, 21 U.S.C. § 841(a), and if so, whether defendants' conduct in this regard should be enjoined pursuant to the injunctive relief provisions of the federal Controlled Substances Act.

See 21 U.S.C. § 882(a). This is the *only* issue before the Court. These lawsuits, for example, do not challenge the constitutionality of Proposition 215, the medical marijuana initiative, as a whole. Nor do they reflect a decision on the part of the federal government to seek to enjoin a local governmental agency from carrying out the humanitarian mandate envisioned by the citizens of this State when they voted to approve this law.

These cases also do not present the question of whether all conduct exempt from prosecution under the state drug laws by Proposition 215 violates federal law. For example, the Court is not deciding whether a seriously ill person who possesses marijuana for personal use upon a physician's recommendation is in violation of federal law. Rather, the sole issue here is whether defendants' conduct, which may be lawful under state law, may nevertheless violate federal law and can thus be enjoined.

Finding that there is a strong likelihood that defendants' conduct violates the Controlled Substances Act, the Court concludes that the Supremacy Clause of the United States Constitution requires that the Court enjoin further violations of the Act.

BACKGROUND

A. *Proposition 215 and the Federal Drug Laws.*

In November 1996, 56% of those participating in the state-wide election voted in favor of Proposition 215, the "Medical Use of Marijuana" initiative, known also as the "Compassionate Use Act" (the "Act"). The Act makes it legal under California law for seriously ill

patients and their primary caregivers to possess and cultivate marijuana for use by the seriously ill patient if the patient's physician recommends such treatment. In particular, it exempts a seriously ill patient, or the patient's primary caregiver, from prosecution under California Health and Safety Code § 11357, relating to the possession of marijuana, and § 11358, relating to the cultivation of marijuana. *See* California Health & Safety Code § 11362.5(d).

As a result of the passage of Proposition 215, several individuals, including defendants, organized "medical cannabis dispensaries" to meet the needs of seriously ill patients. These nonprofit dispensaries provide marijuana to seriously ill patients upon a physician's recommendation. According to defendants, these patients previously had to purchase marijuana, if they were able to purchase it at all, on the black market at exorbitant prices and of questionable quality.

At the time that California's voters approved the initiative, federal law—the Comprehensive Drug Abuse Prevention and Control Act of 1970 (the "Controlled Substances Act")—did, and still does, strictly prohibit the manufacture and distribution of marijuana, and the possession of marijuana with the intent to manufacture or distribute. *See* 21 U.S.C. § 841(a)(1). In particular, the Controlled Substances Act established a comprehensive regulatory scheme which placed controlled substances in one of five "Schedules" depending on each substance's potential for abuse, the extent to which each may lead to psychological or physical dependence, and whether each has a currently accepted medical use in the United States. *See* 21 U.S.C. § 812(b). Congress determined that "Schedule I" substances have a "high

potential for abuse," "no currently accepted medical use in treatment in the United States," and a lack of accepted "safety for use of the drug or substance under medical supervision." 21 U.S.C. § 812(b)(1). Schedule I substances are strictly regulated; no physician may dispense any Schedule I controlled substance to any patient outside of a strictly controlled research project registered with the DEA, and approved by the Secretary of Health and Human Services, acting through the Food and Drug Administration ("FDA"). *See* 21 U.S.C. § 823(f). Congress placed marijuana in Schedule I at the time it passed the Controlled Substances Act and its designation has not changed since then. *See* 21 U.S.C. § 812(c)(c)(10) [*sic*].

B. ***The California Courts and Proposition 215.***

In *People v. Trippet*, 56 Cal. App. 4th 1532, 66 Cal.Rptr.2d 559 (1997), the California Court of Appeal, First District, interpreted Proposition 215 for the first time in a published decision. It held that although Proposition 215 does not exempt a seriously ill patient and her primary caregiver from Health and Safety Code § 11360, which prohibits the transportation of marijuana, a defendant in a criminal case might have a Proposition 215 defense to a charge of illegally transporting marijuana if "the quantity transported and the method, timing and distance of the transportation are reasonably related to the patient's current medical needs." *Trippet*, 56 Cal. App. 4th at 1550-51, 66 Cal. Rptr.2d 559. The court reasoned that Proposition 215 would make no sense if a patient's primary caregiver would be guilty of a crime for "carrying otherwise legally cultivated and possessed marijuana down a hall-

way to the patient's room." *Id.* at 1550, 66 Cal.Rptr.2d 559.

Three months later, a different division of the same court decided *People ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383, 70 Cal.Rptr.2d 20 (1997). A unanimous court held that the defendants in that action, Dennis Peron and the San Francisco Cannabis Cultivators Club, both defendants here, are not primary caregivers within the meaning of the statute. A majority of that court disagreed with *Trippet* by also holding that while Proposition 215 exempts seriously ill patients and their caregivers from California law prohibiting the possession and cultivation of marijuana (Health & Safety Code § 11357, § 11358), it does not, under any circumstances, exempt them from Health and Safety Code § 11359 and § 11360, which prohibit the sale or giving away of marijuana. *Id.* at 1392, 70 Cal. Rptr.2d 20. The California Supreme Court denied review of that decision on February 25, 1998.

C. *The Federal Lawsuits.*

Less than a month after the *Peron* decision, and more than a year after California's voters approved Proposition 215, the United States filed six separate lawsuits against six independent cannabis dispensaries and individuals associated with the management of the dispensaries.[1] The federal government alleges that

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[1] The defendants in the related actions are: Cannabis Cultivators Club and Dennis Peron (98-0085); Marin Alliance for Medical Marijuana and Lynette Shaw (98-0086); Ukiah Cannabis Buyers' Club, Cherrie Lovett, Marvin Leherman and Mildred Leherman (98-0087); Oakland Cannabis Buyers' Cooperative and Jeffrey Jones (98-0088); Flower Therapy Medical Marijuana Club,

defendants' manufacture and distribution of marijuana, and possession with the intent to manufacture and distribute marijuana, violates 21 U.S.C. § 841(a)(1); defendants' use of a facility (i.e., the locations of the dispensaries) for the purpose of manufacturing and distributing marijuana violates 21 U.S.C. § 856(a)(1); and that the individual defendants' conspiracy to violate the Controlled Substances Act violates 21 U.S.C. § 846. The lawsuits seek to preliminarily and permanently enjoin defendants' conduct pursuant to the statute which provides the federal district courts with jurisdiction to enjoin violations of the Controlled Substances Act. *See* 21 U.S.C. § 882(a).

On the same day the federal government filed its lawsuits, it filed motions for a preliminary injunction, permanent injunction and summary judgment in each action. In support of its motions, the government submitted the affidavits of several government agents who attest to their undercover purchases of marijuana from defendants at the various defendant dispensaries.

The six lawsuits were randomly assigned to various judges of this District. Pursuant to Local Rule 3-12, all six were reassigned to this Court as related cases. The Court held a status conference on January 30, 1998, to address defendants' request for additional time to respond to the federal government's motions. At the status conference, and in their papers in support of their request for a continuance, defendants advised the Court that they strenuously dispute the factual assertions in the affidavits with respect to the sale of

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John Hudson, Mary Palmer and Barbara Sweeney (98-0089); and Santa Cruz Cannabis Buyers Club (98-0245).

marijuana to non-seriously ill persons and persons without a physician's recommendation, and contend that much of the federal government's evidence was obtained in violation of the fourth amendment. Over the federal government's objection, the Court granted defendants an extension of time to respond. The Court further ordered that

> [f]or purposes of plaintiff's motions, the parties shall assume that defendants' alleged conduct falls squarely within that permitted by California Proposition 215, California Health & Safety Code § 11362.5. For example, the parties shall assume that all defendants are "primary caregivers" within the meaning of the statute, that all persons to whom defendants distribute or dispense marijuana are seriously ill, and that a physician has determined that the person's health would benefit from the use of marijuana and has made an oral or written recommendation to that effect. Whether the government illegally obtained the evidence upon which it bases its motions shall not be addressed at this time.

February 9, 1998 Order. By its Order, the Court sought to avoid a factual dispute as to whether Proposition 215 applies to defendants' conduct.

Prior to the hearing on the federal government's motions, defendants filed a motion to dismiss for lack of jurisdiction on the ground that Congress does not have authority under the Commerce Clause to regulate defendants' conduct. Defendants also moved to dismiss on the ground that the Court should abstain pursuant to various abstention doctrines.

The Court also received memoranda in opposition to the federal government's motion from *amici curiae* City and County of San Francisco, as represented by the San Francisco District Attorney, and other cities in which defendant dispensaries are located. The City and County of San Francisco and the other cities urge the Court not to adopt the injunctive relief sought by the federal government because of the adverse consequences an injunction would have on the public health of their citizens. In particular, the San Francisco District Attorney asks the Court to limit any injunction so as not to exclude distribution to those patients for whom marijuana is a medical necessity, possibly by the City and County of San Francisco itself. *See* Memorandum of *Amicus Curiae* District Attorney of San Francisco at 11.

The Court held a hearing on all pending motions on March 24, 1998. All parties, and *amici curiae* San Francisco District Attorney, argued at the hearing. The Court requested that the parties submit additional briefing on issues raised at the hearing and took the matter under submission on April 16, 1998.

DISCUSSION

The Supremacy Clause of Article VI of the United States Constitution mandates that federal law supersede state law where there is an outright conflict between such laws. *See Gibbons v. Ogden*, 22 (9 Wheat) U.S. 1, 210, 6 L.Ed. 23 (1824); *Free v. Bland*, 369 U.S. 663, 666, 82 S. Ct. 1089, 8 L.Ed.2d 180 (1962); *Industrial Truck Ass'n, Inc. v. Henry*, 125 F.3d 1305, 1309 (9th Cir. 1997) (state law is preempted "where it is impossible to comply with both state and federal require-

ments, or where state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress"). Recognizing this basic principle of constitutional law, defendants do not contend that Proposition 215 supersedes federal law, 21 U.S.C. § 841(a). Indeed, Proposition 215 on its face purports only to exempt certain patients and their primary caregivers from prosecution under certain *California* drug laws—it does not purport to exempt those patients and caregivers from the federal laws. One of the ballot arguments in favor of the initiative in fact states: "Proposition 215 allows patients to cultivate their own marijuana simply because federal law prevents the sale of marijuana and a state initiative cannot overrule those laws." *Peron*, 59 Cal.App.4th at 1393, 70 Cal.Rptr.2d 20 (quoting Ballot Pamphlet, Proposed Amends. to Cal. Const. with arguments to voters, Gen.Elec. (Nov. 5, 1996 p. 60)).

Defendants argue instead that the Court should dismiss the federal government's actions on abstention grounds and on the ground that 21 USC § 841(a) exceeds Congress's authority under the Commerce Clause. Assuming that the Court has jurisdiction, defendants' arguments fall into three categories: (1) defendants have not violated the federal law; (2) defendants have valid defenses to their violation of the law; and (3) equitable principles preclude injunctive relief. We now turn to each of these arguments.

I. Jurisdiction.

A. *Abstention.*

We start with the proposition that the federal courts have an "unflagging obligation" to exercise their jurisdiction. *See Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817, 96 S. Ct. 1236, 47 L.Ed.2d 483 (1976); *Miofsky v. Superior Court*, 703 F.2d 332, 338 (9th Cir. 1983). While the defendants have asked the Court to abstain, abstention is an "extraordinary and narrow exception to the duty of a district court to adjudicate a controversy properly before it." *Colorado River Water Conservation Dist.*, 424 U.S. at 813, 96 S. Ct. 1236 (quoting *County of Allegheny v. Frank Mashuda Co.*, 360 U.S. 185, 189, 79 S. Ct. 1060, 3 L.Ed.2d 1163 (1959)). Defendants contend that the "extraordinary and narrow" exception to this duty exists here under *Burford*, *Pullman* or *Colorado River*, abstention doctrines.

1. *Burford* Abstention.

Burford abstention is based on comity. It may be appropriate if the lawsuit involves difficult questions of state law, resolution of which is a matter of substantial local concern transcending the result in the case at bar. Federal courts may abstain in such cases if federal adjudication would be disruptive of state efforts to establish a coherent policy with respect to the matter at issue. *See New Orleans Public Service, Inc. v. City Council of New Orleans*, 491 U.S. 350, 362, 109 S. Ct. 2506, 105 L.Ed.2d 298 (1989); *Burford v. Sun Oil Co.*, 319 U.S. 315, 334, 63 S. Ct. 1098, 87 L.Ed. 1424 (1943). *Burford* abstention is appropriate only if the following factors are met:

> (1) that the state has concentrated suits involving the local issue in a particular court; (2) the federal issues are not easily separable from complicated state law issues with which the state courts have special competence; and (3) that federal review might disrupt state efforts to establish a coherent policy.

Tucker v. First Maryland Savings & Loan, Inc., 942 F.2d 1401, 1404-05 (9th Cir. 1991).

Defendants contend that questions of who is a "primary caregiver" within the meaning of Health and Safety Code § 11362.5, and precisely what conduct is permitted by Proposition 215, are difficult and uncertain issues of state law. For example, defendants contend that there is a question whether Proposition 215 exempts the transportation as well as cultivation and use of medical marijuana from California's drug laws. *Compare Peron*, 59 Cal. App. 4th at 1393-95, 70 Cal.Rptr.2d 20 *with Trippet*, 56 Cal. App. 4th at 1550-51, 66 Cal. Rptr.2d 559. They also assert that "medical marijuana" is "a policy problem of substantial import," the importance of which transcends the result in this case. They assert that "[b]y potentially invalidating Proposition 215 on preemption grounds, this court would effectively halt California's attempt to make section 11362.5 compatible with federal law." Defendants' Memorandum in Support of Motion to Dismiss at 7.

These lawsuits, however, are not appropriate candidates for *Burford* abstention. At a minimum, the second requirement for such abstention is not present. The federal issue—whether defendants' conduct vio-

lates federal law—is unrelated to the state questions identified by defendants, whether defendants' conduct is legal under state law. Proposition 215 may exempt defendants' conduct from prosecution under California's criminal laws and, for purposes of the federal government's motion, the Court has assumed that it does. But the only issue in these lawsuits is whether defendants' conduct violates federal law. *See New Orleans Public Service, Inc.*, 491 U.S. at 362, 109 S. Ct. 2506 (*Burford* abstention is inappropriate where federal issues control).

None of the cases cited by defendants in support of *Burford* abstention involved a lawsuit, such as these, where the resolution of the state law issues was immaterial. In *Fireman's Fund Ins. Co. v. Quackenbush*, 87 F.3d 290 (9th Cir. 1996), for example, the Ninth Circuit affirmed the district court's application of *Burford* abstention to an action challenging the constitutionality of Proposition 103 (insurance rate rollback initiative) because the federal issues were "intimately conjoined" with difficult and unresolved issues of state law. *Id.* at 297. Here, in contrast, the scope of Proposition 215 is not at issue since the constitutionality of the initiative is not being challenged. All that is at issue in these actions is whether defendants' conduct violates federal law. The Court need not examine state law to answer that question.

2. *Pullman* Abstention.

Defendants' opposition memorandum argued that abstention is appropriate under an additional doctrine, *Railroad Comm'n of Texas v. Pullman Co.*, 312 U.S. 496, 61 S. Ct. 643, 85 L.Ed. 971 (1941). Under *Pullman*

abstention a federal court may defer hearing a case when "'a federal constitutional issue . . . might be mooted or presented in a different posture by a state court determination of pertinent state law.'" *C-Y Development Co. v. City of Redlands*, 703 F.2d 375, 377 (9th Cir. 1983) (quoting *County of Allegheny v. Frank Mashuda Co.*, 360 U.S. 185, 189, 79 S. Ct. 1060, 3 L.Ed.2d 1163 (1959)). A lawsuit must meet three criteria for *Pullman* abstention to be appropriate:

> (1) the complaint must touch a sensitive area of social policy into which the federal courts should not enter unless there is no alternative to adjudication; (2) a definitive ruling on the state issues by a state court could obviate the need for constitutional adjudication by the federal court; and (3) the proper resolution of the potentially determinative state law issue is uncertain.

Kollsman v. City of Los Angeles, 737 F.2d 830, 833 (9th Cir. 1984). Defendants submit that the Court should abstain until the California courts have had an opportunity to define more clearly what state law permits in order to minimize any conflict between state and federal laws.

Pullman abstention is nonetheless inappropriate because the second criterion, and therefore the third, are inapplicable. As stated above, whether state law permits defendants' conduct, and to what extent it permits defendants' conduct, is immaterial. The issue here is whether that conduct is prohibited by federal law. Thus, a definitive ruling on the state issues, i.e., the scope of Proposition 215, will not obviate the need for deciding the constitutional issues presented by this

lawsuit, including the alleged due process right to be free from pain.

3. *Colorado River* Abstention.

In the interest of "wise judicial administration," federal courts may stay a case involving a question of federal law where a concurrent state action is pending in which substantially similar issues are raised. *See Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800, 817, 96 S. Ct. 1236, 47 L.Ed.2d 483 (1976). "[F]ederal abstention and deference to parallel state proceedings is appropriate under *Colorado River* even when none of the more established doctrines apply." *Fireman's Fund*, 87 F.3d at 297. While no one factor is determinative, the Supreme Court has listed a number of factors to consider in deciding whether such abstention is appropriate. These factors include, "the desireabilty of avoiding piecemeal litigation," and "the order in which the jurisdiction was obtained by the concurrent forums," *Colorado River*, 424 U.S. at 818-19, 96 S. Ct. 1236; whether the state court proceedings are adequate to "protect the federal litigant's rights," *Moses H. Cone Memorial Hospital v. Mercury Construction Corp.*, 460 U.S. at 23, 103 S. Ct. 927; and the risk of conflicting results. *See Colorado River*, 424 U.S. at 818, 96 S. Ct. 1236.

Defendants assert that the state proceeding in *People v. Peron* is substantially similar to these actions since it involves a challenge to the same conduct at issue here and seeks the same relief sought here—an injunction.

The Court concludes, however, that the *People v. Peron* proceeding is not substantially similar. First, it does not involve all the parties to this lawsuit. Thus, the federal government's interests in these actions with respect to the defendants who are not defendants in *Peron* may not be adequately represented by that proceeding. Second, the issues are different. In *Peron*, the State seeks to enjoin defendant Peron's conduct on the ground that it violates state law; that is, that it does not fall within the conduct permitted by Proposition 215. Here, in contrast, the federal government seeks to enjoin defendants' conduct on the ground that it violates federal law; it is immaterial whether that conduct falls within that permitted by Proposition 215. Since the issues are not similar there is no risk of conflicting results. None of the cases cited by defendants involved a situation like here, where the federal government seeks to enforce federal law in federal court. In such a situation, this Court is required to exercise its jurisdiction.

B. *Interstate Commerce Clause.*

Since there is no basis for abstention, we now turn to the question of jurisdiction. Congress has the authority to regulate an activity pursuant to the Commerce Clause of the United States Constitution if the activity regulated falls into one of three categories:

> First, Congress may regulate the use of the channels of interstate commerce. . . . Second, Congress is empowered to regulate and protect the instrumentalities of interstate commerce, or persons or things interstate commerce, or persons or things in interstate commerce, even though the threat may

> come only from intrastate activities. . . . Finally Congress' commerce authority includes the power to regulate those activities having a substantial relation to interstate commerce.

United States v. Lopez, 514 U.S. 549, 558-59, 115 S. Ct. 1624, 131 L.Ed.2d 626 (1995) (citations omitted). In *Lopez*, the Supreme Court held that the Gun-Free School Zones Act of 1990 ("School Zones Act") exceeds Congress's Commerce Clause authority. The School Zones Act made it a federal offense "for any individual knowingly to possess a firearm at a place that the individual knows, or has reasonable cause to believe, is a school zone." 18 U.S.C. § 922(q)(1)(A)(1988 ed. Supp. V). The Court held that the School Zones Act "has nothing to do with 'commerce' or any sort of economic activity. . . . and is not an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated." *Id.* at 561, 115 S. Ct. 1624. It noted that neither the statute nor the legislative history included any congressional findings regarding the effects of gun possession in a school zone on interstate commerce, and rejected the government's theories as to such effects. *Id.* at 562, 115 S. Ct. 1624.

Defendants contend that this Court is without jurisdiction to hear these related cases because Congress does not have the authority to regulate defendants' conduct under the Commerce Clause, just as it does not have authority to regulate possession of a firearm in a school zone. They submit that all of their activities are purely intrastate; therefore, pursuant to *Lopez*, the

Controlled Substances Act is unconstitutional as applied to them.

Congress has the power "to declare that an entire class of activities affects commerce." *Maryland v. Wirtz*, 392 U.S. 183, 192, 88 S. Ct. 2017, 20 L.Ed.2d 1020 (1968). "The only question for the courts then is whether the class is within the reach of the federal power." *Id.*; *see also United States v. Darby*, 312 U.S. 100, 120-21, 61 S. Ct. 451, 85 L.Ed. 609 (1941) (where "Congress itself has said that a particular activity affects the commerce," the only function of a court "[i]n passing on the validity of legislation . . . is to determine whether the particular activity regulated or prohibited is within the reach of the federal power"). "Where the class of activities is regulated and that class is within the reach of federal power, the courts have no power 'to excise, as trivial, individual instances' of the class." *Perez v. United States*, 402 U.S. 146, 154, 91 S. Ct. 1357, 28 L.Ed.2d 686 (1971).

Congress has made detailed findings that the *intrastate* manufacture, distribution, and possession of controlled substances, as a class of activities, "have a substantial and direct effect upon interstate commerce." 21 U.S.C. § 801(3). In particular, Congress found that, "after manufacture, many controlled substances are transported in interstate commerce," *id.* § 801(3)(A); that "controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution," *id.* § 801(3)(B); that "controlled substances possessed commonly flow through interstate commerce immediately prior to such possession," *id.* § 801(4); that "[l]ocal distribution and possession of controlled substances

contribute to swelling the interstate traffic in such substances," *id.* § 801(4); and that "[c]ontrolled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate," *id.* § 801(5). Therefore, "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic." *Id.* § 801(6). Since *Lopez* was decided, the Ninth Circuit has held that Congress's enactment of the Controlled Substances Act is constitutionally permissible under the Commerce Clause. *See United States v. Bramble*, 103 F.3d 1475, 1479-80 (9th Cir. 1996); *United States v. Tisor*, 96 F.3d 370, 373-75 (9th Cir. 1996), *cert. denied*, 519 U.S. 1140, 117 S. Ct. 1012, 136 L.Ed.2d 889 (1997); *United States v. Kim*, 94 F.3d 1247, 1249-50 (9th Cir. 1996); *United States v. Staples*, 85 F.3d 461, 463 (9th Cir.), *cert. denied*, 519 U.S. 938, 117 S. Ct. 318, 136 L.Ed.2d 233 (1996).

Defendants respond that the Ninth Circuit cases are inapplicable to the facts of these actions because those cases involved (1) conduct that was prohibited under state law; and (2) intrastate illicit drug trafficking activities in the same "class of activities" as those interstate activities prohibited by the Controlled Substances Act. Here, in contrast, defendants argue that their conduct—the distribution of marijuana to seriously ill patients for the patient's personal medical use—is not within that class of activities and does not substantially effect interstate commerce.

There can be no debate that when Congress passed the Controlled Substances Act it was primarily concerned with traditional for-profit drug trafficking

rather than the not-for-profit supply of medical marijuana to seriously patients in accordance with state law. Even assuming, however, that defendants' activities are within a different "class of activities" from that which Congress expressly considered, their activities are not within a class that, by its nature, does not have a substantial effect on interstate commerce. Whereas defendants' conduct in the particular instances at issue here may not have had any effect on intrastate commerce, and for purposes of the federal government's motion the Court assumes that at an evidentiary hearing defendants could prove that all marijuana was cultivated locally, distributed locally, and consumed locally by California residents, it is not true that the class of activities within which defendants' conduct falls—non-profit distribution of medical marijuana—necessarily does not affect interstate commerce.

Medical marijuana may be grown locally, or out of the state or country, and there is nothing in the nature of medical marijuana that limits it to intrastate cultivation. Similarly, it may be transported across state lines and consumed across state lines. In *Lopez*, in contrast, the class of activities prohibited—mere *possession* of a firearm near a school—does not have a substantial effect on interstate commerce. This case, unlike *Lopez*, is not about mere possession but rather about distribution, a class of activities that, even if done for the humanitarian purpose of serving the legitimate health care needs of seriously ill patients, can affect interstate commerce.

To hold that the Controlled Substances Act is unconstitutional as applied here would mean that in every

action in which a plaintiff seeks to prove a defendant violated federal law, an element of every case-in-chief would be that the defendant's specific conduct at issue, based on facts proved at an evidentiary hearing or trial, substantially affected interstate commerce. No case so holds and the Court declines to do so for the first time here. Accordingly, the Court has jurisdiction to hear this matter.

II. The Federal Government's Motion.

We now turn to the relief sought by the federal government and whether the federal government has met its burden.

A. *The Motion for a Preliminary Injunction is the Only Motion Before the Court.*

The federal government styled its moving papers as a motion for "preliminary injunction, permanent injunction and summary judgment." It filed this hybrid motion the same day it filed the six related lawsuits. Defendants correctly object to the motion for summary judgment on the ground that the Federal Rules of Civil Procedure permit a motion for summary judgment by a plaintiff "at any time after the expiration of 20 days from the commencement of the action." Fed. R. Civ. P. 56(a). The federal government's motion for summary judgment was thus premature. The federal government contends that it orally renoticed the motions during the scheduling conference on January 30, 1998. The Court's February 9, 1998 Order, however, set the briefing schedule for the federal government's motion for *preliminary injunction* only; it made no mention of a motion for summary judgment. If the federal govern-

ment believed the Court was in error, it had an obligation to so notify the Court and the defendants at that time. As it failed to do so, the only federal government motion pending is the motion for a preliminary injunction.

B. *Preliminary Injunction Standard.*

The general standards for a preliminary injunction are well-established. The court considers: (1) likelihood of success on merits; (2) possibility of irreparable harm to the moving party if the injunction is not granted; (3) the balance of hardships; and (4) in certain cases, whether the public interest will be advanced by granting preliminary relief. *See Miller v. California Pacific Medical Center*, 19 F.3d 449, 456 (9th Cir. 1994); *United States v. Odessa Union Warehouse Co-op*, 833 F.2d 172, 174 (9th Cir. 1987). The moving party must show "either (1) a combination of probable success on the merits and the possibility of irreparable harm, or (2) the existence of serious questions going to the merits, the balance of hardships tipping sharply in its favor, and at least a fair chance of success on the merits." *Miller*, 19 F.3d at 456 (quoting *Senate of California v. Mosbacher*, 968 F.2d 974, 977 (9th Cir. 1992)). "These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases." *Odessa Union*, 833 F.2d at 174.

The standard is modified somewhat when the federal government seeks to enforce a statute:

> In statutory enforcement cases where the government has met the "probability of success prong" of the preliminary injunction test, we presume it has

> met the "possibility of irreparable injury" prong because the passage of the statute is itself an implied finding by Congress that violations will harm the public. Therefore, further inquiry into irreparable injury is unnecessary. However, in statutory enforcement cases where the government can make only a "colorable evidentiary showing" of a violation, the court must consider the possibility of irreparable injury.

United States v. Nutri-cology, Inc., 982 F.2d 394, 398 (9th Cir. 1992). Since this is an action by the federal government to enforce a statute, the injunction must be granted if the federal government establishes a probability of success on the merits since, in such cases, the possibility of irreparable harm is presumed.

Defendants argue that the Ninth Circuit has suggested that if the defendants do not concede a statutory violation, the presumption of irreparable harm does not apply. *See Miller*, 19 F.3d at 459 (noting that in *Odessa Union* "the traditional requirement of irreparable injury was inapplicable because the parties conceded that the federal statute involved was violated"). *Miller*, however, specifically held that the presumption applies if the defendant concedes the statutory violation *or* the government demonstrates "that it is likely to prevail on the merits." *Id.* at 460.

Defendants also contend that the presumption of irreparable harm, even if it may apply, is rebuttable. In *Miller* and *Nutri-cology*, however, the Ninth Circuit held that if the government establishes a likelihood of success on the merits, "further inquiry into irreparable harm is unnecessary." *Miller*, 19 F.3d at 459; *Nutri-*

cology, 982 F.2d at 398. Such a presumption is not unique to government statutory enforcement actions. In copyright actions, the party claiming infringement enjoys a similar presumption of irreparable harm upon a showing of likelihood of success on the merits. *See, e.g., Apple Computer v. Formula Int'l Inc.*, 725 F.2d 521, 525 (9th Cir. 1984).

Thus, before deciding whether the presumption of irreparable injury applies in these cases, the Court must determine if the federal government has established a probability of success on the merits, or only a colorable evidentiary showing, or neither.

C. ***Probability of Success on the Merits.***

Federal law prohibits the knowing or intentional manufacture, distribution, or possession with intent to manufacture or distribute a controlled substance. *See* 21 U.S.C. § 841(a). It is undisputed that marijuana is a controlled substance within the meaning of § 841(a). It is equally undisputed that defendants distribute marijuana. Defendants do not challenge the federal government's evidence to the extent it establishes that defendants provide marijuana to seriously ill patients or their primary caregivers for personal use by the patient upon a physician's recommendation.

Defendants contend that the federal government has nonetheless not established a probability of success on the merits because it has not proved that federal law applies to defendants' conduct. In particular, defendants submit that (1) federal law applies only to illicit or illegal distribution of marijuana, and not to medical marijuana which is legal under state law; (2)

defendants are "joint users" and therefore cannot be guilty of "distribution"; and (3) defendants are exempt from the law as "ultimate users." Defendants argue alternatively that even if the law applies to their conduct, the common law defense of necessity justifies their conduct and, in any event, the statute as applied violates substantive due process.

1. Whether Federal Law Reaches Defendants' Conduct.

a. *Proposition 215 and Federal Law.*

Section 903 of the Controlled Substances Act provides that no provision of the Act

> shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. Defendants argue that this section places the burden on the federal government to prove that state law, Health and Safety Code § 11362.5, is in positive conflict with federal law, 21 U.S.C. § 841(a), and that there is no way the two can stand together. The federal government cannot meet that burden, they contend, because "[i]t is unreasonable to believe that use of medical marijuana by this discrete population for this limited purpose [medical treatment] will create a significant drug problem." *Conant v. McCaffrey*, 172 F.R.D. 681, 694 n. 5 (N.D. Cal. 1997).

Defendants' argument misapprehends the scope of Proposition 215, federal law, and these lawsuits. Defendants are correct that Proposition 215 does not conflict with federal law, but not for the reasons advanced by defendants, i.e., that medical marijuana is not illegal. Proposition 215 does not conflict with federal law because on its face it does not purport to make legal any conduct prohibited by federal law; it merely exempts certain conduct by certain persons from the California drug laws. Thus, whether defendants' conduct falls within the scope of Proposition 215 is immaterial. Defendants do not argue, as they cannot, that simply because state law does not prohibit their conduct federal law may not do so. *See United States v. Rosenberg*, 515 F.2d 190, 198 n. 14 (9th Cir. 1975).

Notwithstanding the operative language of Proposition 215, its declared purpose—"[t]o ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes." ". . . and that such patients and their primary caregivers are not subject to criminal prosecution or sanction," Health & Safety Code § 11362.5(A) & (B)—suggests that California's voters want to exempt medical marijuana from prosecution under federal, as well as state law, even if that is not what they enacted. A state law which purports to legalize the distribution of marijuana for any purpose, however, even a laudable one, nonetheless directly conflicts with federal law, 21 U.S.C. § 841(a). Section 841 prohibits the distribution of marijuana except for use in an approved research project. It does not exempt the distribution of marijuana to seriously ill persons for their personal medical use.

b. *Joint Users Defense.*

In *United States v. Swiderski*, 548 F.2d 445 (2d Cir. 1977), defendants, husband and wife, were charged with violating 21 U.S.C. § 841(a) by possessing cocaine with intent to distribute. *See id.* at 447. The Second Circuit held that "a statutory 'transfer' could not occur between two individuals in joint possession of a controlled substance simultaneously acquired for their own use." *United States v. Wright*, 593 F.2d 105, 107 (9th Cir. 1979) (discussing *Swiderski*). The court thus concluded that the trial judge erred by denying "the jury the opportunity to find that the defendants, who bought the drugs in each other's physical presence, intended merely to share the drugs" and thus, not to distribute them. *Id.*; *Swiderski*, 548 F.2d at 450.

Defendants contend that like the defendants in *Swiderski*, they have not violated the federal law prohibiting the distribution of marijuana. At a trial on the merits they submit that they will prove that their control of medical marijuana is established "through a cooperative enterprise, shared equally among all of the members thereto, for the exclusive medicinal use of each of them, individually" and that no third parties are involved and "nor is anyone else brought into a 'web' of drug use." They also contend that they "do not give money to others for the purposes of procuring drugs for recreational use," rather, they "act in concert as cooperatives to ensure the safe and affordable access to cannabis for medicinal purposes for each of the members." Defendants' Opposition Memorandum at 21. For purposes of the federal government's motion for preliminary injunction, the Court will assume that

defendants could produce evidence to support their offer of proof.

Swiderski, and the other cases cited by defendants, involved the question of whether the defendants in those actions were entitled to a "joint users" jury instruction. The issue here, however, is whether the federal government has established that it is likely to prevail at trial in establishing that *Swiderski* does not apply to defendants' conduct. The Court concludes that it has. *Swiderski* involved a simultaneous purchase by a husband and wife who testified they intended to use the controlled substance immediately. Applying *Swiderski* to a medical marijuana cooperative would extend *Swiderski* to a situation in which the controlled substance is not literally purchased simultaneously for immediate consumption. In light of the fact that *Swiderski* has never been so extended, and in light of the fact that it has not been adopted by the Ninth Circuit, the Court concludes that it is reasonably likely that such a defense would not prevail at a trial addressing whether injunctive relief should be granted.

The Court cautions, however, that it is not ruling that defendants are not entitled to such a defense at trial or in a contempt proceeding for violation of a preliminary or permanent injunction, or that defendants could not as a matter of law defeat a motion for summary judgment with evidence of mere possession. The Court's ruling is narrow. Based on defendants' offer of proof, which does not include any detailed factual allegations, the Court concludes that the federal government is likely to prevail at trial.

c. *Ultimate User Defense.*

Defendants contend that they have not violated the Controlled Substances Act because they are "ultimate users." An "ultimate user" is "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household." 21 U.S.C. § 802(25). Defendants are not ultimate users because they have not lawfully obtained the marijuana at issue. As stated above, the fact that it may be lawful under state law for defendants to cultivate and possess marijuana for medical purposes, does not make it lawful under federal law—the only law at issue here. At present, the only way in which marijuana may be lawfully obtained is in a controlled research setting conducted pursuant to a FDA approved protocol, and where the researcher has been registered with the DEA. *See* 21 U.S.C. § 823(f); 21 C.F.R. § 1301.13(e).

2. The Medical Necessity Defense.

Defendants argue that even if the Controlled Substances Act prohibits their conduct, the injunction must nevertheless be denied because they are entitled to the common law defense of necessity. To invoke the defense, defendants must prove (1) that they were faced with a choice of evils and chose the lesser evil; (2) they acted to prevent imminent harm; (3) they reasonably anticipated a direct causal relationship between their conduct and the harm to be averted; and (4) that there were no legal alternatives to violating the law. *See United States v. Aguilar*, 883 F.2d 662, 693 (9th Cir. 1989). Several state courts have recognized the applicability of the necessity defense in marijuana criminal

prosecutions. *See, e.g., State v. Hastings*, 118 Idaho 854, 801 P.2d 563 (1990); *State v. Diana*, 24 Wash. App. 908, 604 P.2d 1312 (1979); *State v. Bachman*, 61 Haw. 71, 595 P.2d 287 (1979).

Defendants submit that they can prove each element of the defense. First, their members will die, go blind, or suffer severe pain without cannabis; yet, obtaining cannabis "is, for many difficult or impossible to obtain." Thus, defendants contend, they are faced with two evils, letting their members die, go blind or suffer severe pain, or risk running afoul of federal law and that they have chosen the lesser evil. They can meet the second and third requirements, they argue, because the harm to be averted is imminent and life-threatening and supplying cannabis to their members is necessary to prevent that harm. Finally, they assert they have no reasonable alternative; for many people legal drugs simply do not work in treating their symptoms and they have no legal or safe alternative to obtaining marijuana.

The federal government responds that defendants do have a legal and reasonable alternative—a petition to reschedule marijuana from a Schedule I to a Schedule II controlled substance. *See* 21 U.S.C. § 811(a). Rescheduling to Schedule II would permit physicians to prescribe marijuana for therapeutic purposes. The Court doubts whether a rescheduling petition is a reasonable alternative for all seriously ill patients whose physicians have recommended marijuana for therapeutic purposes. For example, such a petition was filed in 1972 and did not receive a final ruling from the Administrator of the Drug Enforcement Agency until 1992, and a final decision on appeal until 1994. *See Alliance*

for Cannabis Therapeutics v. Drug Enforcement Administrator, 15 F.3d 1131 (D.C. Cir. 1994). Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem.

The Court, however, need not dispositively decide whether a reasonable alternative exists. The Court concludes that the federal government is likely to prevail at trial on its claim that the defense of necessity does not preclude the granting of the injunctive relief sought here. As the federal government points out, the defense of necessity has never been allowed to exempt a defendant from the criminal laws on a blanket basis. To put it another way, for the defense to be available here, defendants would have to prove that each and every patient to whom it provides cannabis is in danger of imminent harm; that the cannabis will alleviate the harm for that particular patient; and that the patient had no other alternatives, for example, that no other legal drug could have reasonably averted the harm. Defendants do not contend that they could offer such proof. For example, they state that they could offer evidence that "for many" people, legal drugs are not effective. That is not the same as saying that for each of every person to whom they provide, and will provide, marijuana, legal drugs are not effective such that marijuana is a necessity.

The Court is not ruling, however, that the defense of necessity is wholly inapplicable to these lawsuits. If a preliminary or permanent injunction is granted, and the federal government alleges that defendants have violated the injunction, there will be specific facts and

circumstances before the Court from which the Court can determine if the jury should be given a necessity instruction as a defense to the alleged violation of the injunction. As such facts are not presently before the Court, it is premature for the Court to decide whether such a defense is available.

By concluding that medical necessity is not an appropriate defense to the issuance of an injunction, the Court is not placing defendants in the difficult position of deciding whether to go forward with their conduct, which they sincerely believe is absolutely necessary, or abiding by the injunction. As defendants point out, with or without the injunction they must decide whether to violate federal law; they are bound by federal law even in the absence of an injunction.

3. Substantive Due Process.

The Due Process Clause of the United States Constitution "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg*, 521U.S. 702, ——, 117 S. Ct. 2258, 2267, 138 L.Ed.2d 772 (1997). Where a "fundamental liberty interest" is involved, government action restricting that interest must be "narrowly tailored to serve a compelling [federal government] interest." *Id.* 117 S. Ct. at 2268; *see also id.* ("the Fourteenth Amendment 'forbids the government to infringe . . . "fundamental" liberty interests at all, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest'" (citation omitted)). A fundamental liberty interest must be " 'deeply rooted in this Nation's history and tradition,'" and " 'implicit in our concept of

ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Id.* (citation omitted). The right must also be "carefully described." *Id.*

Defendants contend that the preliminary injunction should be denied because the relief sought—an order enjoining defendants from the manufacture or distribution, or possession with intent to distribute marijuana, or conspiring to do the same—violates their substantive due process rights. In particular, defendants assert that such an injunction would infringe their fundamental right to be free from unnecessary pain, to receive palliative treatment for a painful medical condition, to care for oneself, and to preserve one's own life. *See generally Washington v. Glucksberg*, 521 U.S. 702, 117 S. Ct. 2258, 138 L.Ed.2d 772; *DeShaney v. Winnebago Cty. Dept. of Social Serv.*, 489 U.S. 189, 200, 109 S. Ct. 998, 103 L.Ed.2d 249 (1989). They argue that they are not asserting a constitutional right to the medical drug of their choice, even if the drug had not been proved effective, as was the case in the actions challenging federal government's restrictions on laetrile, *see, e.g., Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980); *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980), but rather that they have a right to "a demonstrated and effective treatment as recommended by their physician that can alleviate their agony, preserve their sight, and save their lives." Defendants' Supplemental Opposition Memorandum at 9.

The Court concludes that the federal government is likely to prevail at trial on the issue of whether defendants have a fundamental right to medical marijuana. The Court, however, is not ruling as a matter of

law that no such right exists. It holds that on the record presently before the Court, defendants have not established that the right to such treatment is "so rooted in the traditions and conscience of our people as to be ranked as fundamental." *Washington v. Glucksberg*, 521 U.S. at ——, 117 S. Ct. at 2268 (quoting *Palko v. Connecticut*, 302 U.S. 319, 325, 58 S. Ct. 149, 82 L.Ed. 288 (1937)). Nor have defendants established that they have standing to assert such a defense as to their distribution of marijuana to seriously ill persons other than themselves.

Moreover, the Court need not dispositively resolve this constitutional issue because even assuming defendants had established that such a fundamental right exists, and that they have standing to assert such a right, this defense, like the defense of necessity, is inapplicable to this injunction action. Defendants are asking the Court to deny the injunction and, in effect, exempt their conduct from the federal laws as a whole. In order for the Court to conclude that defendants have a substantive due process defense to an injunction barring them from violating federal law, the Court would have to find that the substantive due process right of each and every patient to whom the defendants will dispense marijuana in the future will be violated if the government prevents defendants from doing so. Such a defense may be available in a contempt proceeding where the trier of fact is presented with a particular transaction to a particular patient under a particular set of facts. *See Washington v. Glucksberg*, 521 U.S. at——n. 24, 117 S. Ct. at 2275 n. 24 (holding that Washington State's ban on assisted suicide is not unconstitutional as applied to terminally ill patients generally, but that the Court's decision does not "fore-

close the possibility that an individual plaintiff seeking to hasten her death, or a doctor whose assistance was sought, could prevail in a more particularized challenge"). It is not available, however, to exempt generally the distribution of medical marijuana from the federal drug laws.

D. *Whether the Preliminary Injunction Should Be Granted.*

For the foregoing reasons, the Court concludes that the federal government has established that it is likely to prevail on the merits of its claim that defendants are in violation of federal law. As set forth above, in a statutory enforcement action brought by the federal government, irreparable harm is presumed if the government establishes that it is likely to prevail on the merits. *Nutri-cology*, 982 F.2d at 398 ("further inquiry into irreparable injury is unnecessary"); *see also id.* ("the passage of the statute is itself an implied finding by Congress that violations will harm the public").

Defendants argue that injunctive relief is nonetheless unwarranted because this Court is sitting as a court of equity and must therefore consider the traditional defenses to the granting of equitable relief, including the unclean hands of the moving party. They contend that these principles, plus the fact that the federal government is seeking injunctive relief at all, require the denial of injunctive relief.

1. The Propriety of Seeking Injunctive Relief.

The government rarely seeks injunctions pursuant to 21 U.S.C. § 882(a). The Court has located only five

published opinions in which the federal government sought relief based on the statute. *See, e.g., United States v. Leasehold Interest in 121 Nostrand Avenue*, 760 F. Supp. 1015, 1035 (E.D.N.Y. 1991); *United States v. Williams*, 416 F. Supp. 611, 614 (D.D.C. 1976). At oral argument, and in their supplemental memoranda, defendants insist that the federal government has chosen to bring a civil injunctive action rather than charge defendants with a violation of the criminal laws, in order to deprive defendants of the same right to a jury trial to which they would be entitled in a criminal action.

Defendants do not contend that the government is attempting to deprive them of a right to a jury in general. 21 U.S.C. § 882(b) provides that "[i]n case of an alleged violation of an injunction or restraining order issued under this section, trial shall, *upon demand of the accused*, be by a *jury* in accordance with the Federal Rules of Civil Procedure." 21 U.S.C. § 882(b) (emphasis added). If the Court issues an injunction, defendants have a right to a jury in any proceeding in which it is alleged that they have violated the injunction. Defendants instead contend that a jury trial in accordance with the Federal Rules of Civil Procedure will provide them with fewer procedural protections than a criminal trial. For example, in civil proceedings a party may make a motion for summary judgment; no such procedure, however, is available in a criminal trial; and in a civil proceeding, under Federal Rule of Civil Procedure 48, a jury may be composed of six persons, whereas in a criminal trial a defendant is guaranteed a trial by a jury of twelve.

These procedural differences do not compel a conclusion that the federal government is acting in bad faith. First, in any contempt proceeding, the Court will determine the appropriate number of jurors, up to twelve, which still must return a unanimous verdict. *See* Fed. R. Civ. P. 48 ("[u]nless the parties otherwise stipulate, (1) the verdict shall be unanimous"). Second, even assuming that the federal government could bring a motion for summary judgment in a contempt proceeding—and it is not clear from the plain language of section 882(b) that it could—summary judgment may be granted, and a party denied the fight to a jury, only if *no reasonable jury* could find for the nonmoving party. *See Matsushita Elec. Ind. Co. v. Zenith Radio*, 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L.Ed.2d 538 (1986).

a. Unclean Hands

The "clean hands" doctrine

> insists that one who seeks equity must come to the court without blemish. . . . This maxim "is a self-imposed ordinance that closes the doors of a court of equity to one tainted with an inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant." . . . This rule applies to the government as well as to private litigants . . .

Equal Employment Opportunity Comm'n v. Recruit U.S.A., 939 F.2d 746, 752 (9th Cir. 1991) (citations omitted). Defendants contend that the federal government comes before this Court with unclean hands because it refuses to acknowledge that marijuana has a medical use and reschedule it as a Schedule II con-

trolled substance which would permit seriously ill patients to be treated with marijuana.

The federal government's conduct is "unclean," defendants assert, because the federal government itself has commissioned studies which have established marijuana's medical efficacy and then ignored these studies. Defendants highlight the fact that while the federal government continues to maintain that there are no medically accepted uses for marijuana, the DEA is simultaneously distributing marijuana to eight people under the Investigative New Drug program for medical purposes. Those eight people were enrolled years ago, defendants submit, before the "war on drugs," and the DEA has refused to enroll any more patients, not because of concerns as to the safety of marijuana, but for political reasons. Defendants also point out that in 1970, Congress appropriated a million dollars for a commission to recommend appropriate marijuana legislation. Public Law 91-513, § 601(e) (Oct. 27, 1970). The commission, known as the "Shafer Commission," recommended decriminalizing possession and casual distribution of small amounts of marijuana. *See Marihuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152 (1972). Congress, however, refused to reschedule marijuana. Finally, defendants argue that the DEA ignored the recommendation of its own Administrative Law Judge that marijuana be changed to a Schedule II controlled substance[.] *See* Defendants' Supplemental Opposition Memorandum at 23.

The federal government disputes that the Shafer Commission recommended decriminalizing marijuana. Rather, it contends the Commission merely recom-

mended increased support for studies to evaluate the efficacy of medical marijuana. *See First Report, supra,* at 176.

The fact remains, however, that medical marijuana advocates have been unsuccessful in convincing the federal government decision makers that marijuana should be reclassified as a Schedule II controlled substance and thus made available to seriously ill patients upon a physician's recommendation. That does not mean that the federal government has acted with unclean hands. Indeed, as late as 1994, a federal court of appeal affirmed the Drug Enforcement Agency Administrator's decision not to reschedule. *See Alliance for Cannabis Therapeutics v. Drug Enforcement Administration,* 15 F.3d 1131 (D.C. Cir. 1994).

The federal government has advised the Court that a petition for reclassification has been filed and that on December 17, 1997, the DEA referred the petition to the Secretary of Health and Human Services ("HHS") upon determining that the petition raised scientific and medical issues that had not previously been evaluated by HHS as part of any prior scheduling action. *See* Federal Government's Post-Hearing Memorandum at 13. One would expect the Secretary to act expeditiously on the petition in light of the expressed concerns of the citizens of California.

CONCLUSION

Because of the Supremacy Clause of the United States Constitution, the only issue before the Court is whether defendants' conduct violates federal law. The Court concludes that the federal government has

established that it is likely that it does. As these lawsuits are brought to enforce a statute, namely, the Controlled Substances Act, irreparable harm is presumed and the injunction must be granted.

Once again, however, the Court must caution as to what this decision does not do. The Court has not declared Proposition 215 unconstitutional. Nor has it enjoined the possession of marijuana by a seriously ill patient for the patient's personal medical use upon a physician's recommendation. Nor has the Court foreclosed the possibility of a medical necessity or constitutional defense in any proceeding in which it is alleged a defendant has violated the injunction issued herein.

Finally, the San Francisco District Attorney has raised the issue of possible local governmental distribution of medical marijuana. Such a question is not before the Court and, in any event, is purely speculative as it is uncertain whether the federal government would even seek to enjoin such conduct by a local government entity under strictly controlled conditions. For example, as the San Francisco District Attorney mentioned at oral argument, the distribution of clean needles to heroin addicts violates federal law, *see* 21 U.S.C. § 863, yet the federal government has not filed suit to enjoin the City and County of San Francisco's distribution of such needles. Indeed, HHS recently stated that community programs promoting the distribution of clean needles reduces the spread of AIDS and does not encourage drug use. *See* Health and Human Services Press Release, "*Research Shows Needle Exchange Programs Reduce HIV Infections Without Increasing Drug Use*" (April 20, 1998). From this publicly stated position, one could conclude that the

federal government will not enforce the drug paraphernalia statute in light of local community efforts to prevent the spread of AIDS. The Court recognizes that local governmental distribution of medical marijuana to seriously ill patients raises political issues which may not require judicial intervention.

Attached to this Memorandum and Order is a proposed form of preliminary injunction in 98-00085. The injunction in each case will be identical except for the name of the defendants and the location of the dispensary. The parties are directed to file a written submission with this Court by 5:00 p.m. on Monday, May 18, 1998 as to the form of the order. The Court will issue the preliminary injunction shortly thereafter.

IT IS SO ORDERED.

[PROPOSED] ORDER

For the reasons stated in its Memorandum and Order dated May 13, 1998, is hereby ORDERED as follows:

1. Defendants Cannabis Cultivators Club and Dennis Peron are hereby preliminarily enjoined, pending further order of the Court, from engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana, in violation of 21 U.S.C. § 841(a)(1); and

2. Defendants Cannabis Cultivators Club and Dennis Peron are hereby preliminarily enjoined from using the premises of 1444 Market Street, San

Francisco, California for the purposes of engaging in the manufacture and distribution of marijuana; and

3. Defendant Dennis Peron is hereby preliminarily enjoined from conspiring to violate the Controlled Substances Act, 21 U.S.C. § 841(a)(1) with respect to the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana.

4. It shall not be a violation of this injunction for defendant Dennis Peron to seek and obtain legal advice from his attorneys.

IT IS SO ORDERED.

APPENDIX H

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Nos. 98-16950, 98-17044, 98-17137
D.C. No. (C98-00088-CRB (Northern California))

UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE;
JEFFREY JONES, DEFENDANTS-APPELLANTS

[Filed: Feb. 29, 2000]

ORDER

Before: SCHROEDER, REINHARDT, and SILVERMAN, Circuit Judges.

The panel as constituted above has voted to deny the Petition for Rehearing and to deny the Petition for Rehearing En Banc.

The full court was advised of the petition for rehearing en banc and no judge of the court has requested to vote on the petition for rehearing en banc. Fed. R. App. P. 35.

The petition for rehearing and the petition for rehearing en banc are denied.

APPENDIX I

1. Section 811 of Title 21 of the United States Code states in relevant part as follows:

Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5. Proceedings for the issuance, amendment, or repeal of such

rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance

should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section.

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

* * * * *

2. Section 812(b)(1) of Title 21 of the United States Code states as follows:

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

3. Section 823(f) of Title 21 of the United States Code states as follows:

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration if he determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

4. Section 841(a) of Title 21 of the United States Code states as follows:

Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

5. Section 882(a) of Title 21 of the United States Code states as follows:

Injunctions

(a) Jurisdiction

The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

5. Pub. L. 105-277, Div. F, 112 Stat. 2681, 760-761, 105th Cong., 2d Sess., (1998) states as follows:

DIVISION F—NOT LEGALIZING MARIJUANA FOR MEDICINAL USE

It is the sense of the Congress that–

(1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;

(2) the consequences of illegal use of Schedule I drugs are well documented, particularly with regard to physical health, highway safety, and criminal activity;

(3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana, heroin, LSD, and more than 100 other Schedule I drugs;

(4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act, before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;

(5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;

(6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

(7) marijuana use by children in grades 8 through 12 declined steadily from 1980 to 1992, but, from 1992 to 1996, has dramatically increased by 253 percent among 8th graders, 151 percent among 10th graders, and 84 percent among 12th graders, and the average age of first-time use of marijuana is now younger than it has ever been;

(8) according to the 1997 survey by the Center on Addition and Substance Abuse at Columbia University, 500,000 8th graders began using marijuana in the 6th and 7th grades;

(9) according to that same 1997 survey, youths between the ages of 12 and 17 who use marijuana are 85 times more likely to use cocaine than those who abstain from marijuana, and 60 percent of adolescents who use marijuana before the age of 15 will later use cocaine; and

(10) the rate of illegal drug use among youth is linked to their perceptions of the health and safety risks of those drugs, and the ambiguous cultural messages about marijuana use are contributing to a growing acceptance of marijuana use among children and teenagers;

(11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circumvent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration; and

(12) not later than 90 days after the date of the enactment of this Act–

(A) the Attorney General shall submit to the Committees on the Judiciary of the House of Representatives and the Senate a report on–

(i) the total quantity of marijuana eradicated in the United States during the period from 1992 through 1997; and

(ii) the annual number of arrests and prosecutions for Federal marijuana offenses during the period described in clause (i); and

(B) the Commissioner of Foods and Drugs shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the specific efforts underway to enforce sections 304 and 505 of the Federal Food, Drug and Cosmetic Act with respect to marijuana and other Schedule I drugs.

3

No. 00-151

Supreme Court, U.S.
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In The

Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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RESTATED QUESTION PRESENTED

Whether a court has equitable discretion to consider a request to modify an injunction where the enjoined party asserts the defense of medical necessity in a civil injunction action under 21 U.S.C. § 882, and establishes through uncontroverted evidence that there is a class of seriously ill patients who would otherwise suffer imminent harm and who have absolutely no other legal alternative.

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BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

The Defendants and Respondents, Oakland Cannabis Buyers' Cooperative and Jeffrey Jones (hereafter collectively "OCBC"), respectfully request that the Petition for a Writ of Certiorari filed by Plaintiff and Appellant the United States of America be denied.

STATEMENT OF THE CASE

Much has occurred since the Court of Appeals issued the opinion that the government now challenges, *United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109 (9th Cir. 1999) (per curiam) ("*OCBC I*"), on September 13, 1999.

On July 25, 2000, the government noticed an appeal from the district court's July 17, 2000, Order (App. 12a-14a) and July 17, 2000, Amended Preliminary Injunction Order (App. 15a-17a). That second appeal, *United States v. Oakland Cannabis Buyers' Cooperative*, Ninth Circuit Case No. 00-16411 ("*OCBC II*"), remains pending. Despite the pendency of *OCBC II*, on July 28, 2000, the government filed a Petition for a Writ of Certiorari.

On August 11, 2000, the Court of Appeals denied the government's request for a stay of the district court's July 17, 2000, Orders. *See* App. A1-A2. The Court of Appeals did, however, accelerate the briefing schedule in *OCBC II*. *See* App. A3-A4.

On August 29, 2000, this Court granted the government's request for a stay of the district court's July 17, 2000 orders "pending final disposition of the appeal by the United States Court of Appeals for the Ninth Circuit and further order of this Court." *United States v. Oakland Cannabis Buyers' Cooperative*, 530 U.S.___, 69 U.S.L.W. 3165 (Aug. 29, 2000). The stay effectively reinstated the broad

preliminary injunction in place before the Court of Appeals issued its opinion in *OCBC I*. Thus, OCBC is not currently permitted to distribute medical cannabis to its seriously ill and dying patients, regardless of whether those patients meet the legal standard for medical necessity set forth in *OCBC I* and the district court's July 17, 2000, Orders. The government now stands in exactly the same position it occupied before the Court of Appeals ruled in *OCBC I*. Justice Stevens dissented from this Court's order issuing the stay, stating:

> Because the [government] has failed in this case to demonstrate that the denial of necessary medicine to seriously ill and dying patients will advance the public interest or that the failure to enjoin the distribution of such medicine will impair the orderly enforcement of federal criminal statutes, whereas [OCBC has] demonstrated that the entry of a stay will cause them irreparable harm, I am persuaded that a fair assessment of that balance favors a denial of the extraordinary relief that the government seeks.

Because of the accelerated briefing schedule set forth in the Court of Appeals' August 11, 2000, Order, briefing was completed in *OCBC II* on October 10, 2000. On October 26, 2000, OCBC requested that the Court of Appeals expedite the disposition of *OCBC II*. *See* App. A5-A14.

REASONS TO DENY THE PETITION

In November 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996 ("The Act"). Cal. Health & Safety Code § 11362.5. "The Act makes it legal under California law for seriously ill patients and their primary caregivers to possess and cultivate marijuana for use by the seriously ill patient if the

patient's physician recommends such treatment. In particular, it exempts a seriously ill patient, or the patient's primary caregiver, from prosecution . . . relating to the possession of marijuana and . . . the cultivation of marijuana." *United States v. Cannabis Cultivators' Club*, 5 F. Supp. 2d 1086, 1091 (N.D. Cal. 1998). Pursuant to Proposition 215, OCBC, a not-for-profit organization, was established to meet the needs of seriously ill and dying patients. OCBC's goal is to provide seriously ill patients with safe access to necessary medicine so that these individuals do not have to resort to the streets, thereby exposing themselves to criminal elements and products of dubious quality.

Also pursuant to California law, the City of Oakland established a medical cannabis distribution program and designated OCBC as the City's agent to administer the program. OCBC is a well-run, professional organization that has served the medical needs of seriously ill patients and has worked with law enforcement to ensure that those with legitimate medical needs may obtain medical-quality cannabis safely, and without fear of criminal involvement.

Despite the fact that the voters of California have spoken, the federal government brought a civil injunctive proceeding under 21 U.S.C. § 882 to block OCBC's distribution of medical cannabis to those suffering from severe illnesses. The government's decision to use Section 882 in this case makes this case virtually unique. According to the district court (Hon. Charles R. Breyer), Section 882 has been used in only five published decisions since Congress enacted it as part of the Controlled Substances Act ("CSA") in 1970. *Cannabis Cultivators' Club*, 5 F. Supp. 2d at 1104. The government has never attempted

to prosecute OCBC criminally under the CSA or any other law.

In May 1998, the district court granted the government's request for a preliminary injunction. *Id.* at 1106. On October 15, 1998, OCBC requested that the district court modify the injunction to allow distribution of cannabis to patients who meet the legal test of necessity derived from *United States v. Aguilar*, 883 F.2d 662 (9th Cir. 1989). The district court summarily denied the requested modification on October 16, 1998, because it concluded it lacked discretion to grant OCBC's motion.

Recognizing the danger to public health and safety posed by the closure of OCBC, on October 27, 1998, the Oakland City Council issued Resolution No. 74618 declaring a Local Public Health Emergency with Respect to Safe, Affordable Access to Medical Cannabis in the City of Oakland. The Resolution found that closure of OCBC impairs public safety, and that OCBC's closure would harm seriously ill Oakland residents. The Resolution declares a public health emergency and urges the federal government to cease actions "that pose obstacles to access to cannabis for Oakland residents. . . . " Resolution No. 74618 (Local Public Health Emergency with Respect to Safe, Affordable Access to Medical Cannabis in the City of Oakland). The City of Oakland has since renewed this resolution every two weeks.

On September 13, 1999, the Court of Appeals issued an opinion in this case explicitly recognizing that seriously ill patients who meet the legal definition of medical necessity may lawfully obtain medical cannabis for their illnesses despite these injunctive proceedings. *OCBC I*, 190 F.3d 1109 (9th Cir. 1999). In so doing, the Court of Appeals reversed the district court's order summarily

denying OCBC's request to modify the injunction to permit distribution to patient-members with a medical necessity, and directed that the district court reconsider its decision. *Id.* at 1114-1115.

The Court of Appeals reasoned:

> The district court summarily denied OCBC's motion, saying that it lacked the power to make the requested modification because "its equitable powers do not permit it to ignore federal law." In doing so, the district court misapprehended the issue. The court was not being asked to ignore the law. It was being asked to take into account a legally cognizable defense that likely would pertain in the circumstances.

Id. at 1114.

The Court of Appeals also held that the district court erroneously failed to weigh the public interest when it summarily denied the requested modification:

> The district court erred in another respect as well. In deciding whether to issue an injunction in which the public interest would be affected, or whether to modify such an injunction once issued, a district court *must* expressly consider the public interest on the record. The failure to do so constitutes an abuse of discretion. . . .

Id. at 1114 (*emphasis added*).

The Court of Appeals (*see OCBC I*, 190 F.3d at 1114-1115) and the district court (*see* App. 12a-14a) have found that a balancing of equities favors such an exception in this case. As the Court of Appeals explained in *OCBC I*:

> OCBC has identified a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses. Indeed,

> the City of Oakland has declared a public health emergency in response to the district court's refusal to grant the modification under appeal here. Materials submitted in support of OCBC's motion to modify the injunction show that the proposed amendment to the injunction clearly related to a matter affecting the public interest. Because the district court believed that it had no discretion to issue an injunction that was more limited in scope than the Controlled Substances Act itself, it summarily denied the requested modification without weighing or considering the public interest.

OCBC I at 1114-1115.

In view of this background, the government's petition seeks review of a dispute that is not ripe for this Court's intervention. The Court of Appeals has not had an opportunity to rule on the merits of the government's appeal from the district court's order modifying the preliminary injunction. The government offers no justification for bypassing the Court of Appeals and deciding issues on a record that is not fully developed. On this basis alone, the petition should be denied.

Moreover, the petition itself presents no "compelling" reason for review as required by Supreme Court Rule 10 and should be denied for this additional reason. The government both mischaracterizes and overstates the significance of *OCBC I*. *OCBC I* neither legalized the use of cannabis by the general public, nor did it make sweeping pronouncements about the applicability of the necessity defense to facts other than those before the Court of Appeals. Rather, the Court of Appeals held that a district court has equitable jurisdiction to consider a request to modify an injunction where the enjoined party presents facts that raise the applicability of the necessity defense. The criteria for necessity that the Court of Appeals

directed the district court to consider, and that the district subsequently adopted, are narrow and specific, and by no means make the drug laws unenforceable, as the government contends. The government remains free after *OCBC I* to prosecute anyone that it believes to be violating the federal drug laws.

OCBC I does not represent a conflict with any circuit, nor does it represent a departure from established precedent or from established judicial proceedings. Sup. Ct. R. 10(a). In remanding the case to the district court, the Court of Appeals in *OCBC I* relied upon controlling precedent (*Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982)) concerning the district courts' traditional equitable discretion to fashion injunctive relief. In this case, the government elected to enforce criminal drug laws through the unusual means of an equitable injunction. Because the government chose this equitable remedy, the Court of Appeals correctly held that "since the government chose to deal with potential violations on an anticipatory basis," the injunction must be "narrow enough to exclude conduct that likely would be legally privileged or justified." *OCBC I*, 190 F.3d at 1114.

In remanding the case to the district court, the Court of Appeals in *OCBC I* also expressly relied upon *United States v. Aguilar*, 883 F.2d 662 (9th Cir. 1989). *Aguilar* has been the law of the circuit for over a decade, it confirms well-established principles regarding necessity, and it creates no conflict with other circuits.

In sum, there is no basis for granting the government's petition. The petition should be denied.

A. The Dispute Is Not Ripe for Review By this Court

The government seeks review of an interlocutory order of the Court of Appeals entered on September 13, 1999, remanding this case to the district court, and directing the district court to exercise its equitable discretion to consider modification of a preliminary injunction prohibiting OCBC from providing medical cannabis to seriously ill patients. Since that order was entered over one year ago, the district court has complied with the remand order. OCBC offered significant new evidence which was not part of the record before the Court of Appeals in *OCBC I*, including additional affidavits from patients and physicians demonstrating that serious medical conditions could be relieved and imminent harm avoided only if the preliminary injunction were modified, and documenting the declaration of a medical emergency by the City of Oakland. Additional briefing was submitted to the district court, including the *Amicus Curiae* Brief of the California Medical Association. At the conclusion of these proceedings, and after the government declined to offer any additional evidence, the district court exercised its equitable jurisdiction to modify the preliminary injunction, exempting from the injunction the distribution of cannabis to a small and narrowly defined group of seriously ill patients who meet the legal criteria for necessity set forth in the amended injunction.

The government has since appealed the district court's order of modification. Rather than intervene with a grant of certiorari while the review of the district court's amended injunction is pending before the Court of Appeals, this Court should await the resolution of the issues currently before the Court of Appeals. If review is then found to be appropriate, this Court will have before

it the entire record, including the proceedings on remand. To limit the Court's review to the original order of remand entered a year ago, while a review of the actual modification after remand is still unresolved, would disrupt the orderly administration of justice, result in piecemeal review, and deprive this Court of a fully developed record.

Although the government has included in the Appendix to its Petition for Certiorari the district court's July 17, 2000, Order [Appendix B] and the Amended Preliminary Injunction Order [Appendix C], these orders are not part of the record they seek to review. The government cannot seriously contend that this Court should bypass the Court of Appeals and rule on the government's appeal from the district court's amended injunction order without first allowing the Court of Appeals to render an opinion regarding that order. *See* 28 U.S.C. §§ 1254(1) & 2101(E); Sup. Ct. R. 11 (certiorari before entry of judgment in the Court of Appeals "will be granted only upon a showing that the case is of such imperative public importance as to justify deviation from normal appellate practice and to require immediate determination in this Court"); *Coleman v. PACCAR, Inc.*, 424 U.S. 1301, 1304 (1976) (Rehnquist, J.) (certiorari before judgment in the Court of Appeals is an "extremely rare occurrence").

This Court generally awaits final judgment in the lower courts before exercising its certiorari jurisdiction. Ordinarily, "this court should not issue a writ of certiorari to review a decree of the Circuit Court of Appeals on appeal from an interlocutory order, unless it is necessary to prevent extraordinary inconvenience and embarrassment in the conduct of the cause." *American Constr. Co. v. Jacksonville, T & K. W. R. Co.*, 148 U.S. 372, 384

(1893). Because the government has obtained a stay of the district court's amended injunction, the government plainly suffers no inconvenience if this Court declines to grant the petition.

In recent years, the Solicitor General has been a strong advocate of the denial of certiorari to review interlocutory orders when such review was sought by criminal defendants. As noted in R. Stern, E. Gressman, S. Shapiro and K. Geller, *Supreme Court Practice*, § 4.18, p. 196 n.60 (7th Ed. 1993):

> Since 1980, the Solicitor General consistently has argued in federal criminal cases that the interlocutory status of a case is a sufficient ground for denial of certiorari when review is sought by a defendant. The Solicitor General has maintained that judicial efficiency would be better served by deferring review until rendition of final judgment, so that all claims can be presented in a single petition if, in fact, the defendant is convicted. The Supreme Court has not granted certiorari in such a situation since 1980, which may reflect its general agreement with the Solicitor General's position.

Although this is not a criminal case, of course, it does involve the enjoining of alleged violations of a federal criminal statute, and the same considerations of judicial efficiency are presented. There are very likely to be other claims to be addressed by this Court in the context of reviewing a final judgment in this matter. In fact, the Court of Appeals deferred considering several significant issues because of the interlocutory nature of OCBC's appeal of the preliminary injunction, including the question of OCBC's complete immunity under the CSA because its officers are local government officials engaged in the enforcement of a law relating to controlled substances. *See* 21 U.S.C. § 885.

In the courts below, OCBC also argued that in light of the Compassionate Use Act of 1996, the Ninth and Tenth Amendments of the Constitution protect OCBC's activities. The lower courts chose not to address these issues, but they provide alternate grounds for the lower courts' decisions. Moreover, OCBC also raised other issues that provide alternate grounds for the Court of Appeals' decision, including violation of patient-members' substantive due process rights.

The pendency of a Court of Appeals' remand has, on numerous occasions, been viewed as a strong reason to deny a petition for a writ of certiorari by this Court. In *Locomotive Firemen v. Bangor & Aroostock R. Co.*, 389 U.S. 327, 328, 560 (1967) (per curiam), this Court denied certiorari to review contempt orders issued against a labor union for violating a temporary restraining order forbidding a strike, because the Court of Appeals had remanded to the district court after resolving the legal issues the petitioner sought to review, to allow the district court to exercise its equitable jurisdiction to review the severity of the sanction. "However, because the Court of Appeals remanded the case, it is not yet ripe for review by this Court. The petition for a writ of certiorari is denied. *Id.* at 328. *See Hamilton-Brown Shoe Co. v. Wolf Bros.*, 240 U.S. 251, 257-258 (1916)." *See generally* R. Stern, E. Gressman, & S. Shapiro, *Supreme Court Practice*, § 4.18, pp. 224-26 (6th Ed. 1986).

Even more closely analogous was the recent case of *Virginia Military Institute v. United States*, 508 U.S. 946 (1993). There, the petitioner sought certiorari after the Court of Appeals vacated a judgment in its favor, and remanded the case to the district court for determination of an appropriate remedy. The petitioner contended that no remedy was appropriate, since the Court of Appeals

erred in finding a constitutional violation in its policy of restricting admission to a state military college to male applicants. This Court denied certiorari, and Justice Scalia authored an opinion noting the importance of the issues raised, but concluding it was prudent to await resolution of the remedy in the courts below. Subsequently, after the district court's remedial order had been upheld by the Court of Appeals, 44 F.3d 1229 (4th Cir. 1995), this Court granted certiorari. 516 U.S. 910 (1995). The issues presented were then resolved on a complete record. *United States v. Virginia*, 518 U.S. 515 (1996).

The issue now pending in the Court of Appeals after the remand will actually present the question the government seeks to review with greater clarity and less ambiguity than the year-old remand order. The question allegedly presented in this case, as posed by the government, is "Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, forecloses a medical necessity defense to the Act's prohibition against manufacturing and distributing marijuana, a Schedule I controlled substance." *See* Petition for a Writ of Certiorari, p. I. The remand order, however, addressed this question only indirectly and tangentially. The question *actually* decided by the Court of Appeals a year ago was whether a district court had equitable jurisdiction to consider a request to modify an injunction where the enjoined party asserts the defense of medical necessity. Now that the remand has been adjudicated, and the district court has modified the injunction to recognize the availability of the defense, the question the government propounds is squarely presented, not to this Court, *but to the Court of Appeals for the first time.* While this Court has the power to grant a writ of certiorari before judgment by the Court of Appeals, in

exercising this power, the Court is guided by the statement in Rule 18 that

> [a] petition for a writ of certiorari to review a case pending in a United States Court of Appeals, before judgment is given in that court, will be granted only upon a showing that the case is of such imperative public importance as to justify deviation from normal appellate practice and to require immediate settlement in this Court.

As noted in R. Stern, E. Gressman, S. Shapiro, and K. Geller, *Supreme Court Practice*, § 4.20, p. 199 (7th Ed. 1993), "[t]he public interest in a speedy determination must be exceptional, however, to warrant skipping the court of appeals in this fashion." Even where this Court has found great public importance, it has awaited Court of Appeals adjudication where the Court of Appeals recognized "the vital importance of the time element in this litigation" and acted in "ample time." *Aaron v. Cooper*, 357 U.S. 566, 567 (1958) (The Little Rock School Desegregation Case). Here, of course, the Court of Appeals has already expedited consideration of the government's appeal from the district court's order entered after remand.

For all these reasons, this dispute is not ripe for review. Accordingly, the petition should be denied.

B. The Law Governing this Case Is Well Settled and Does Not Require Clarification on Certiorari

1. *OCBC I* Correctly Directed the District Court to Exercise Its Equitable Jurisdiction

OCBC I does not depart from established legal precedent, and the issue determined in that case – the equitable jurisdiction of the district court – does not warrant review by this Court. As Justice Stevens recognized, the

issues raised in the present petition are governed by controlling Supreme Court precedent: *Romero-Barcelo*, 456 U.S. 329-330. *See United States v. Oakland Cannabis Buyers' Cooperative*, 530 U.S.___, 69 U.S.L.W. 3165 (Aug. 29, 2000) (Stevens, J., dissenting). *Romero-Barcelo* and many other Supreme Court and Court of Appeals' decisions[1] hold that when, as in Section 882, Congress grants the district courts jurisdiction to issue civil injunctions to enjoin future federal statutory violations, "[t]he [mere] grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation." *Romero-Barcelo*, 456 U.S. at 313. Instead, absent an "unequivocal statement of [Congress'] purpose" to "make such a drastic departure from the traditions of equity practice" by making issuance of an injunction mandatory, an injunction is not mandatory even if the conduct to be enjoined indisputably violates

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[1] *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 541-542 (1987); *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946); *The Hecht Co. v. Bowles*, 321 U.S. 321, 330 (1944); *Brown v. Swann*, 35 U.S. (10 Pet.) 497, 503 (1836); *United States v. Marine Shale Processors*, 81 F.3d 1329, 1358-1361 (5th Cir. 1996); *Sierra Club v. Federal Deposit Ins. Corp.*, 992 F.2d 545, 551-552 (5th Cir. 1993); *Northern Cheyenne Tribe v. Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988) (cited in *OCBC I*, 190 F.3d at 1114); *The Fund for Animals, Inc. v. Lujan*, 962 F.2d 1391, 1400 (9th Cir. 1992); *Natural Resources Defense Council, Inc. v. Texaco Refining & Mktg., Inc.*, 906 F.2d 934, 938-939 (3rd Cir. 1990); *National Labor Relations Bd. v. P*I*E* Nationwide, Inc.*, 894 F.2d 887, 893 (7th Cir. 1990); *The Town of Huntington v. Marsh*, 884 F.2d 648, 651-652 (2d Cir. 1989); *Kinney v. Pioneer Press*, 881 F.2d 485, 490-491 (7th Cir. 1989); *National Wildlife Fed'n v. Burford*, 835 F.2d 305, 323-324 (D.C. Cir. 1987); *Flynn v. United States By and Through Eggers*, 786 F.2d 586, 591 (3rd Cir. 1986).

federal law. *The Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). The showing of Congressional intent must be compelling, because such an intent overrides centuries of judicial practice and tradition:

> We are dealing here with the requirements of equity practice with a background of several hundred years of history. . . . The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mold each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied . . . . [I]f Congress desired to make such an abrupt departure from traditional equity practice as is suggested, it would have made its desire plain. Hence we resolve the ambiguities of [the Act] in favor of that interpretation which affords a full opportunity for equity courts to treat enforcement proceedings . . . in accordance with their traditional practices, as conditioned by the necessities of the public interest which Congress has sought to protect.

The Hecht Co., 321 U.S. at 329-330.

Romero-Barcelo's discussion of *TVA v. Hill*, 437 U.S. 153 (1978), upon which the government relies confirms just how rare it is – and how compelling the showing of Congressional intent must be – before this Court will hold that Congress intended to deprive the district courts of their traditional equitable discretion to fashion injunctive relief. In *Hill*, the issue was whether, by enacting the Endangered Species Act, Congress intended to deprive

the district court of its traditional equitable discretion to grant or deny an injunction barring completion of a dam that, if it became operational, would inevitably cause the extinction of an endangered species, the snail darter. This Court held in *Hill* that Congress had deprived the district court of its discretion and had mandated that an injunction issue. In *Romero-Barcelo*, this Court explained that the injunction in *Hill* was mandatory because an injunction was the *only* way to fulfill the Congressional objective of the Endangered Species Act. *Romero-Barcelo*, 456 U.S. at 314. "The purpose and language of the statute under consideration in *Hill*, not the bare fact of a statutory violation, compelled that conclusion." *Id.* at 313. In contrast, in *Romero-Barcelo*, "[a]n injunction [was] not the *only means* of insuring compliance" with federal law. *Id.* at 314. (*emphasis added*). This was so because the statute at issue in *Romero-Barcelo*, the FWCPA, like the statute at issue in this case, the CSA, 21 U.S.C. § 801 et seq., provided for *criminal penalties* in addition to a civil injunction. *Romero-Barcelo*, 456 U.S. at 314. Thus, an agency enforcing the FWCPA can ensure that Congress' goals are fulfilled by prosecuting violations under the FWCPA's criminal provisions, regardless of whether it also obtains an injunction, just as the Justice Department can under the CSA.

Accordingly, this case is indistinguishable from *Romero-Barcelo* and the result should be the same in both cases: the district court had discretion to refuse to enjoin some or all of the defendants' conduct, even if that conduct indisputably violated federal law. This Court made itself clear in *Romero-Barcelo*, and the Court of Appeals followed its prior case law interpreting *Romero-Barcelo* (*Northern Cheyenne Tribe v. Hodel*, 851 F.2d 1152, 1155-56 (9th Cir. 1988)) when it decided *OCBC I*. *See* 190 F.3d at 1114.

There is another critical point that must be emphasized: *None* of the equitable grounds the district courts relied on in *Romero-Barcelo, Amoco,* and *The Hecht Company* amounted to a legally cognizable affirmative defense to the substantive federal law violations that the plaintiffs unsuccessfully sought to enjoin. Thus, *Romero-Barcelo, Amoco,* and *The Hecht Company* each implicitly hold that the district court may partly or completely deny equitable relief in the face of an undisputed violation of federal law, based *solely* on equitable grounds, *whether or not* those grounds would be legally cognizable defenses in a criminal prosecution or in a civil suit for damages or civil penalties.

2. The CSA Does Not Evidence an Unequivocal Statement of Intent to Divest the District Court of its Traditional Equitable Power

In *OCBC I,* the Court of Appeals reversed the district court's order denying OCBC's request to modify the preliminary injunction to exempt from its scope patients who satisfied the legal test for medical necessity drawn from *United States v. Aguilar,* 883 F.2d 662 (9th Cir. 1989). The government fails to identify anything on the face of the CSA or in its legislative history that provides the "unequivocal statement" of intent to deprive the district court of this authority, as required by this Court's precedents. *The Hecht Co.,* 321 U.S. at 329. There is nothing in the text of Section 882 or in the legislative history of Section 882 to support the government's position. *See* H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4624; S. Rep. No. 91-613, at 33 (1969). Indeed, section 882(a) provides *broad* authority to the district court to issue injunctions: "The district courts of the United States

and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of [the CSA]."

Moreover, the legislative history of the CSA itself shows that Congress had no information upon which to make any judgment about the medical necessity of cannabis when it enacted the CSA in 1970 and thus could not have intended to circumscribe the district court's equitable powers to preclude any consideration of medical necessity. Congress placed cannabis only tentatively in Schedule I when it enacted the CSA in 1970. Congress itself admitted that it did not have a firm understanding of cannabis. Months before it enacted the CSA, Congress enacted the Marihuana and Health Reporting Act, Pub. L. No. 91-296, §§ 501-503, 1970 U.S.C.C.A.N. 418, which directed the Secretary of the Department of Health, Education, and Welfare ("HEW") to prepare a report within 90 days and annually thereafter, "containing current information on the health consequences of using marihuana" and "containing such recommendations for legislative and administrative action as he may deem appropriate." *Id.* Congress ordered this report because it had found that "notwithstanding the various studies carried out, and research engaged in, with respect to the use of marihuana, there is a lack of an authoritative source for obtaining information involving the health consequences of using marihuana." *Id.*

On August 14, 1970, during the debates on the CSA but before the HEW report was to be completed, HEW advised Congress as follows:

> Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by a

> schedule I or even a schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue.

H.R. Rep. No. 91-1444 (1970), reprinted in 1970 U.S.C.C.A.N. at 4579 & 4629. Congress also received a list of facts and "fables" about cannabis from the Director of the National Institute of Mental Health, which included the fact that cannabis is not physically addictive and the fact that use of cannabis does not necessarily lead to violence or the use of other drugs. *Id.* at 4577-78.

Congress acknowledged this debate and its own uncertainty, stating: "The extent to which marihuana should be controlled is a subject upon which opinions diverge widely." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4577. Congress struck a compromise in response to this uncertainty. On the one hand, it tentatively placed cannabis on Schedule I, which includes substances that have "a high potential for abuse," "no currently accepted medical use in treatment in the United States, and for which "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision." 21 U.S.C. § 812(b)(1) & (c), Schedule 1(c). But, to resolve the uncertainty about whether cannabis belongs on Schedule I, Congress created the bipartisan Commission on Marihuana and Drug Abuse (the "Shafer Commission"), and directed it to prepare a report to guide Congress. *Id.*; *see* Act of Oct. 14, 1970, Pub. L. No. 91-513, § 601, 1970 U.S.C.C.A.N. (84 Stat.) 1489-90.

The Shafer Commission recommended that Congress amend the CSA, and that the states amend their laws, so that possession of cannabis for personal use would not

subject the possessor to punishment, even as a misdemeanor, and "casual distribution of small amounts of marihuana for no remuneration, or insignificant remuneration not involving profit would no longer be an offense." *Marihuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152-153 (1972). The Shafer Report also confirmed that too little was known about the medical benefits of cannabis and recommended further study. *Id.* at 176.

Based on the foregoing, there is nothing in the legislative history of the CSA to support the conclusion that Congress intended to foreclose the district courts from exercising their traditional equitable discretion to incorporate a medical necessity exception into an injunction so that seriously ill and dying individuals who satisfy the legal test of medical necessity may obtain medical cannabis from an agency authorized by California law and supported by the City of Oakland and local law enforcement agencies.

Nor can the government rely on the "Sense of Congress" proclamation. The "Sense of Congress," which is buried in the Omnibus Consolidated and Emergency Supplementary Appropriations Act, 1999, Pub L. 105-277, 112 Stat. 2681-760 to 2681-761, does not have the force of law. *See Yang v. California Dept. of Social Servs.*, 183 F.3d 953, 961-62 (9th Cir. 1999) (Sense of Congress provision buried in Budget Act merely "non-binding, legislative dicta"); *see also, e.g., Boos v. Barry*, 485 U.S. 312, 327-28 (1988) (noting that proposed statute repealing District of Columbia law had been changed to Sense of Congress resolution to avoid violating home rule for District of Columbia); *Lyng v. Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439, 455 (1988) (finding that provision was only statement of policy in part based on remark of bill's sponsor that it

was a "[S]ense of Congress joint resolution"). The "Sense of Congress" does not mention Section 882(a), much less purport to limit the district courts' equitable discretion under Section 882(a) or under any other statute. Accordingly, the "Sense of Congress" proclamation falls far short of being the "unequivocal statement of [Congressional] purpose" to "make such a drastic departure from the traditions of equity practice," that must exist before an Act of Congress can override a district court's equitable discretion. *See The Hecht Co.*, 321 U.S. at 329.

3. The CSA's Rescheduling Procedures Do Not Deprive the District Court of Equitable Power to Modify an Injunction to Recognize Medical Necessity Upon a Proper Showing

The government also suggests that the very existence of the administrative procedures for rescheduling cannabis limits the district court's equitable jurisdiction and makes the medical necessity defense legally unavailable. The government is mixing apples and oranges, however. When the Attorney General reclassifies a drug in a rulemaking proceeding under the CSA or the FDA approves a drug under the Federal Food Drug and Cosmetic Act ("FFDCA"), the legal treatment of the drug profoundly and universally changes. The approval or rescheduling governs its use in *all* cases for *all* purposes and for *all* individuals. *OCBC I* did not purport to make such a sweeping change in how cannabis is treated under the law. Instead, the district court merely refused the government's request to enjoin use by an extremely narrow group of seriously ill patients who meet the legal standard of medical necessity.

Nothing in *United States v. Rutherford*, 442 U.S. 544 (1979) requires a contrary result. In *Rutherford*, plaintiffs brought an *affirmative* case to exempt laetrile, an unproven drug, from the requirements of the FFDCA. OCBC does not seek that relief here and *OCBC I* did not direct the district court to grant such relief. There also was no claim in *Rutherford* that laetrile was the *only* effective treatment for the patients, and indeed there was a significant concern that these patients would forego conventional treatment in favor of laetrile. In contrast, OCBC's patient-members with a medical necessity are the target of a civil injunction action brought by the government to preclude their use of the *only* medicine that has proven effective in relieving their conditions or symptoms, pursuant to the rigorous and narrowly tailored doctrine of necessity. As the Court of Appeals recognized, if the government had sought to prosecute Respondents individually, they would have been able to litigate the issue of necessity in due course. *OCBC I*, 190 F.2d at 1114. Respondents should not be penalized because the government sought to proceed by injunction.

In this case, the administrative process continued over the course of nearly three decades. Further administrative proceedings are not a reasonable alternative for the seriously ill patients protected by the district court's amended injunction. As recognized by the district court, "it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to alleviate a current medical problem." *Cannabis Cultivators' Club*, 5 F. Supp. 2d at 1102.

C. The CSA Does Not Abrogate the Medical Necessity Defense

As discussed in Section A, *supra*, the question of whether medical necessity is available as a defense to a claimed violation of the CSA is not directly presented by the instant petition. Accordingly, consideration of that issue by this Court is premature. Even if this issue were directly presented by government's petition, however, there is no reason to conclude that the lower courts decided this issue incorrectly.

1. Nothing in the CSA Suggests that Congress Intended to Foreclose a Defense of Medical Necessity

The government points to no explicit expression of an intent by Congress to eliminate a well-recognized defense – necessity – from the CSA. Necessity is one of the oldest and most well-entrenched common law defenses in Anglo-American jurisprudence whose roots can be traced to the mid-Thirteenth Century in England, and earlier on the Continent. *See* Reeve, *Necessity: The Right To Present a Recognized Defense*, 21 New Eng. L. Rev. 779, 781-784 (1985-86); Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 U.C.L.A. L. Rev. 409 (1981); Arnolds & Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. Crim. L. & Criminology 289 (1974). Contrary to the government's contention, recognition of a necessity defense does not undermine the rule of law. "[T]he necessity defense proclaims legal some conduct which, in other contexts, would plainly be illegal. . . . *The defense is not aimed at subverting existing laws or at hastening their demise. Rather, the defense simply recognizes that, in certain circumstances, the choice made by the defendant is a choice that*

society would also have made and now is given the opportunity to ratify." United States v. Dorell, 758 F.2d 427, 436 (9th Cir. 1985) at 436 (Fergusen, J., concurring) (*emphasis added*).

Moreover, Courts should be particularly reluctant to assume the legislature has foreclosed the justification of necessity when, as in this case, the justification arises in the context of an individual's assertion of a constitutionally protected right. Where the constitutional right at stake is the individual's constitutionally protected autonomy with regard to his own health decisions, a claim of necessity must rank especially high.

Indeed, in the context of medical cannabis, the District of Columbia court carefully noted the constitutional protection given to an individual's personal health decisions in upholding an individual's claim of necessity to justify the use of cannabis to save his sight from the ravages of glaucoma:

> "[A] law which apparently requires an individual to submit to deteriorating health without proof of a significant public interest to be protected raises questions of constitutional dimension."

United States v. Randall, 104 Daily Wash. L. Rep. 2249, 2253 n.29 (D.C. Super. 1976).

The government points to nothing in the text or legislative history of the CSA that evidences any intent to abrogate a medical necessity defense. As discussed in Section B.2 *supra*, Congress had no information upon which to make any judgment about the medical necessity of cannabis when it enacted the CSA in 1970. Act of Oct. 14, 1970, Pub. L. No. 91-513, 84 Stat. 1236, codified as amended at 21 U.S.C. §§ 801 *et seq.*

Moreover, absent some unambiguous statement by Congress that it intended to eliminate necessity as a

defense, the CSA, a criminal statute, cannot be read to preclude that defense in *all* circumstances. *See United States v. Granderson*, 511 U.S. 39, 49 (1994) (the government cannot rely on general statements that Congress intended to "get tough on drug offenders"; instead, the government must point to specific evidence that Congress expressed intent on the narrow issue in question). The CSA must be interpreted using "the ancient rule of statutory construction that penal statutes should be strictly construed against the government . . . and in favor of the persons on whom the penalties are sought to be imposed." 3 Sutherland Stat. Const. § 59.03, p. 102 (5th ed.). When, as in this case, the "text, structure, and history fail to establish that the government's position is unambiguously correct – [courts] apply the rule of lenity and resolve the ambiguity in [the defendant's] favor." *Granderson*, 511 U.S. at 54.

In this case, there is nothing in the text of the CSA suggesting that Congress intended to abrogate the ancient, universally applicable common law defense of necessity. Accordingly, the lower courts' recognition of the defense to exempt those with a medical necessity is consistent with well-established law.

Finally, the "Sense of Congress" does not evidence an intent to eliminate necessity as a defense to a claimed violation of the CSA. The "Sense of Congress" does not purport to amend the CSA, expressly or by implication. The plain language of the "Sense of Congress" merely reaffirms that cannabis can be moved from Schedule I and thus legalized for medical use by the general public *only* through the administrative process set out in the

CSA. Because neither *OCBC I* nor the district court purported to move cannabis from Schedule I of the CSA to some other schedule or generally to legalize medical cannabis *across the board* for *all* people under *all* circumstances, the "Sense of Congress" has no bearing on the issues before this Court. Moreover, the "Sense of Congress" does not specifically mention the common law defense of medical necessity. In the absence of an unambiguous statement of an intent to foreclose that defense under the CSA, the defense remains available.

2. Recognition of a Defense of Medical Necessity for Cannabis Use Is Not Inconsistent with the Classification of Marijuana on Schedule I of the CSA

Under Section 812(b)(1) of the CSA, substances may be classified on Schedule I for the following reasons: (1) the substance has a high potential for abuse; (2) the substance has no accepted medical use in treatment in the United States; and (3) there is a lack of accepted safety for use in treatment of the substance under medical supervision. The government argues that because a Schedule I drug by definition has "no currently accepted medical use," any justification for use asserted on the basis of "medical necessity" could not have been within legislative contemplation. This argument necessarily presumes that the terms "accepted medical use in treatment" and "medical necessity" are equivalent expressions and have exactly the same meaning. These concepts plainly serve different purposes, however. While "medical necessity" focuses on the urgent needs of a specific patient, the term "accepted medical use in treatment" applies to use by the general public as a whole. Accordingly, there is no reason to conclude that the Schedule I classification has any

bearing on the availability of a medical necessity exception for a single patient.

The validity of the government's position turns on what Congress meant by the phrase "accepted medical use in treatment" in defining Schedule I controlled substances. In construing the term, first resort should be to the plain meaning of the words used. *Caminetti v. United States*, 242 U.S. 470, 485 (1917). The words used suggest that a medical use is one that is generally accepted by the medical community.

The legislative history of the CSA confirms the importance to be attached to the opinions of qualified medical experts. During hearings before the House Subcommittee on Foreign and Interstate Commerce, representatives of pharmaceutical companies and medical researchers voiced concern that the Federal Bureau of Narcotics and Dangerous Drugs would have total authority to determine whether drugs have accepted medical uses in treatment. Addressing this concern, Deputy Chief Counsel for the BNDD, Michael Sonnenreich, testified that the determination of accepted medical use "will be made by the medical community." Drug Abuse Control Amendments – 1970: Hearings Before the Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce, House of Representatives, 91st Cong., 2d Sess. (1970) at 698. There is also a parallel between the phrase "accepted medical use" and the standard widely used to determine the competency and admissibility of scientific evidence, *i.e.*, whether there is general acceptance of a technique in the relevant scientific community. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).[2] Reliability of evidence does not depend

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[2] In *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 594 (1993), the court held that Federal Rule of Evidence 702

upon unanimous belief or universal agreement, however. The admissibility standard implicitly recognizes that even a technique that is not generally accepted could nevertheless be effective in an individual situation. Similarly, a patient could consent to a unique form of medical treatment that is not generally accepted, as long as the risks were fully explained. A physician administering such treatment would not be engaged in malpractice.

So understood, an "accepted medical use" is one that would be generally recognized by medical experts as being reliable and effective for general medical purposes based upon widely available safety and efficacy studies. Consequently, a medical use that is efficacious only in a unique, special, or isolated individual case would, for that reason alone, not constitute an "accepted medical use." Thus, a Schedule I drug is one that does not have a recognized or *generally* accepted medical use, even though it might have an effective individualized or idiosyncratic use.

Viewed from this perspective, the concept of "medical necessity" reflects the reality of medical practice. A physician can freely resort to the generally accepted pharmacopoeia in the general treatment of patients. But when generally accepted treatments are ineffective, the physician and the patient may jointly agree that medical necessity requires treatment that is not generally accepted. The medical necessity test applies to a particular patient or class of patients, and provides a safety valve for the individual patient who has exhausted other treatments. The CSA's criteria are not at war with good medical

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replaced the *Frye* test, but that "general acceptance" is still a relevant consideration in determining admissibility of scientific evidence.

practice, and good medical practice requires that physicians keep searching, even when conventional, "generally accepted" remedies do not work.

Finally, the legal test for "generally accepted medical use" and the legal test for medical necessity are quite different and serve different purposes. In *Alliance for Cannabis Therapeutics v. Drug Enforcement Admin.*, 15 F.3d 1131 (D.C. Cir. 1994), the court upheld a new five-part test formulated by the DEA to determine whether a drug is in "currently accepted medical use":

(1) The drug's chemistry must be known and reproducible;

(2) There must be adequate safety studies;

(3) There must be adequate and well-controlled studies proving efficacy;

(4) The drug must be accepted by qualified experts;

(5) The scientific evidence must be widely available.

Id. at 1135, citing 57 Fed. Reg. at 10,506. These guidelines are intended to scrutinize a drug for use by the *general public*. The legal standard for medical necessity is quite different, however. It requires a showing by: "[1] people with serious medical conditions [2] for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; [3] who will suffer serious harm if they are denied cannabis; and [4] for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects. *OCBC I*, 190 F.3d at 1115. The medical necessity test applies to a *particular patient*, and provides a safety valve for a person who must act to prevent a greater harm. Thus, the two standards have no bearing on each other.

CONCLUSION

OCBC I has no impact on the government's ability to prosecute individuals for violating federal drug laws. Because this is not a criminal prosecution, neither the Court of Appeals nor the district court had any occasion to decide whether and how the medical necessity defense would apply in a criminal prosecution. Instead, *OCBC I* dealt *only* with whether the district court has equitable discretion to shape a civil preliminary injunction under 21 U.S.C. § 882 so that it excludes those who satisfy a narrowly defined four-part medical necessity test to save lives and reduce suffering. The Court of Appeals has had no opportunity to review the district court's July 17, 2000, orders, and this Court has stayed those orders. Thus, there is no reason for this Court to intervene in a case that is not yet ripe for its review. For these reasons, the government's petition should be denied.

Respectfully Submitted,

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October 30, 2000.

APPENDIX TO BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellant, v. OAKLAND CANNABIS BUYERS' COOPERATIVE, Defendant-Appellee.	No. 00-16411 DC# CV-98-88-CRB Northern California ORDER (Filed Aug. 11, 2000)

Before: SCHROEDER, REINHARDT and SILVERMAN, Circuit Judges

This panel accepts appeal no. 00-16411 as a comeback matter relating to *United States of America v. Oakland Cannobis Buyers' Coop.*, 190 F.3d 1109, (9th Cir. 1999) (per curiam). The Clerk shall so note on the docket, and forward further filings in this appeal to this panel.

Appellant's opposed emergency motion under Circuit Rule 27-3 for a stay pending appeal and Supreme Court review is DENIED.

The briefing schedule established on July 28, 2000, is vacated. The appeal filed July 25, 2000, is a preliminary injunction appeal. Accordingly, Ninth Circuit Rule 3-3

shall apply. The Clerk shall reset the briefing schedule accordingly.

MEMORANDUM TO CLERK
Pursuant to General Order
No. 6.9, I certify that
Judges MMS, SR + BGS
concur in this order and
authorize its filing.

/s/ Curt Pham
Motions Attorney

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellant, v. OAKLAND CANNABIS BUYERS' COOPERATIVE, Defendant-Appellee.	No. 00-16411 DC# CV-98-88-CRB Northern California ORDER (Filed Aug. 11, 2000)

This is a preliminary injunction appeal. Accordingly, Ninth Circuit Rule 3-3 shall apply, and the briefing schedule is set as follows. If they have not already done so, within 7 days after entry of this order, the parties shall make arrangements to obtain from the court reporter an official transcript of proceedings in the district court which will be included in the record on appeal. The opening brief is due August 22, 2000; the answering brief is due September 19, 2000; and the optional reply brief is due within 14 days of service of the answering brief. *See* 9th Cir. R. 3-3(b).

If appellant fails to file timely the opening brief, this appeal will be dismissed automatically by the Clerk for failure to prosecute. *See* 9th Cir. R. 42-1.

For the Court

/s/ Curt Pham
Curt Pham
Motions Attorney/Deputy Clerk
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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellant, v. OAKLAND CANNABIS BUYERS' COOPERATIVE, Defendant-Appellee.	No. 00-16411 DC# CV-98-88-CRB Northern California ORDER (Filed Oct. 10, 2000)

Appellee's motion for leave to file an oversized answering brief is granted. The Clerk shall file the answering brief served on September 19, 2000.

Appellant's motion for an extension of time to file the reply brief is granted. The reply brief is now due October 10, 2000.

Upon receipt of the reply brief, this case will be ready for calendaring.

For the Court

Cathy A. Catterson
Clerk/Court Executive

By

/s/ Manning Evans
Manning Evans
Motions Attorney/
Deputy Clerk

No. 00-16411

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Defendants-Appellees.

Appeal from Order Modifying Injunction by the United States District Court for the Northern District of California
Case No. C 98-00088 CRB
entered on July 17, 2000, by Judge Charles R. Breyer.

APPELLEES' MOTION TO EXPEDITE APPEAL

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This is an appeal from an order modifying a preliminary injunction, entered by the district court on July 17, 2000. The merits panel that heard the first appeal in this case, Schroeder, Reinhardt, and Silverman, JJ., retained jurisdiction to decide this appeal. *See United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109, 1115 (9th Cir. 1999) *(OCBC I), petn. for cert. filed* July 28, 2000.

On August 11, 2000 the merits panel issued two orders that struck a balance between the interests of the Appellees, the Oakland Cannabis Buyers' Cooperative and Jeffrey Jones (collectively "OCBC"), and the Appellant, the United States. On the one hand, the panel denied the Government's request for a stay of the district court's July 17, 2000 Order. On the other hand, the panel ordered that briefing be expedited pursuant to Ninth Circuit Rule 3-3(b) (preliminary injunction appeals).

Despite the August 11, 2000 Order, the Government moved for a seven-day extension of time to file its reply brief, up to and including October 10, 2000. OCBC opposed the Government's motion. The motion was granted in an Order filed on October 10, 2000. The October 10, 2000 Order was signed by Manning Evans, Motions Attorney/Deputy Clerk. It does not state whether the Government's motion was referred to or considered by the merits panel.

The case is now fully briefed. Because the merits panel that decided *OCBC I* retained jurisdiction, this case, unlike most preliminary injunction appeals, will not be "referred to the next available motions/screening panel for disposition." Ninth Circuit Rule 3-3(d). Instead, it must be referred to the prior merits panel for disposition. *See id.*

OCBC respectfully requests that this case be placed before the merits panel for disposition as soon as possible and that all further proceedings be expedited. *See* Ninth Circuit Rule 3-3(e) ("If a party files a motion to expedite the appeal . . . , the Court may order a . . . procedure for disposition of the appeal that differs from the schedule and procedure set forth in subparagraphs (b) and (d)."); Ninth Circuit Rule 27-12 ("Motions to expedite . . . hearing may be filed and will be granted upon a showing of good cause."); *see also* 28 U.S.C. § 1657(a) ("Notwithstanding any other provision of law, each court of the United States shall . . . expedite consideration of any action . . . for temporary or preliminary relief. . . . "); *Coalition for Economic Equity v. Wilson*, 122 F.3d 692, 699 (9th Cir.) (noting the "priority and expedited decision that we must give appeals from preliminary injunctions under 28 U.S.C. § 1657 and Ninth Circuit Rule 3-3"), *cert. denied*, 522 U.S. 963 (1997); *Gregorio T. v. Wilson*, 54 F.3d 599, 600 (9th Cir. 1995) ("28 U.S.C. § 1657 and Ninth Circuit Rule 34-3 give priority to preliminary injunction appeals. In addition, recently adopted Ninth Circuit Rule 3-3 (effective July 1, 1995) automatically expedites briefing and decision in preliminary injunction appeals.").

OCBC seeks expedited consideration because of the United States Supreme Court's ruling in *United States v. Oakland Cannabis Buyers' Club*, 530 U.S. ___, 69 U.S.L.W. 3165 (Aug. 29, 2000). After this Court issued its August 11, 2000 Order denying the Government's motion to stay the district court's July 17, 2000 Order, the Government requested a stay from Supreme Court Justice Sandra Day O'Connor, sitting as the Circuit Justice for the Ninth Circuit. Justice O'Connor referred the Government's

application to the full Court, which granted the Government's application by a vote of 7 to 1, with Justice Breyer not participating. The Supreme Court stayed the July 17, 2000 Order the Government challenges in this appeal, "pending final disposition of the appeal by the United States Court of Appeals for the Ninth Circuit and further order of this Court." Justice Stevens dissented, stating:

> Because the [Government] has failed in this case to demonstrate that the denial of necessary medicine to seriously ill and dying patients will advance the public interest or that the failure to enjoin the distribution of such medicine will impair the orderly enforcement of federal criminal statutes, whereas [OCBC has] demonstrated that the entry of a stay will cause them irreparable harm, I am persuaded that a fair assessment of that balance favors a denial of the extraordinary relief that the government seeks.

OCBC's opposition to the Government's petition for certiorari review of *OCBC I* is due on and will be filed on Monday, October 30, 2000.

The Supreme Court's stay ruling effectively reinstated the broad preliminary injunction that this Court reversed in *OCBC I*. Thus, the Government now has all the relief it seeks, and OCBC is in the same position it occupied before this Court ruled in *OCBC I:* OCBC is enjoined from distributing medicinal cannabis to its seriously ill and dying patients, regardless of whether those patients satisfy the four-part test for medical necessity set forth in *OCBC I* and in the district court's July 17, 2000 Order.

This Court has recognized how critical it is that OCBC's patients receive the medicinal cannabis they so desperately need:

> OCBC has identified a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses. Indeed, the City of Oakland has declared a public health emergency in response to the district court's refusal to grant the modification under appeal here. Materials submitted in support of OCBC's motion to modify the injunction show that the proposed amendment to the injunction clearly related to a matter affecting the public interest. . . .
>
> OCBC submitted the declarations of many seriously ill individuals and their doctors who, despite their very real fears of criminal prosecution, came forward and attested to the need for cannabis in order to treat the debilitating and life threatening conditions.
>
> In short, OCBC presented evidence that there is a class of people with serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects.
>
> The government, by contrast, has yet to identify any interest it may have in blocking the

> distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes. It has offered no evidence to rebut OCBC's evidence that cannabis is the only effective treatment for a large group of seriously ill individuals, and it confirmed at oral argument that it sees no need to offer any. It simply rests on the erroneous argument that the district judge was compelled as a matter of law to issue an injunction that is coextensive with the facial scope of the statute.

OCBC I, 190 F.3d at 1114-1115. This Court implicitly reconfirmed its conclusions by denying the Government's stay motion on August 11, 2000.

Because of the Supreme Court's August 29, 2000, stay order, every day that this appeal remains pending is another day that OCBC's patients will not receive the medicinal cannabis they so desperately need. Every day will also be another day on which the will of the People of the State of California, expressed in Proposition 215 and the ordinances passed by the City of Oakland, is frustrated.

OCBC respectfully requests that this Court expedite the disposition of this appeal to the fullest extent possible. If this Court concludes that oral argument would be beneficial, OCBC respectfully requests that it schedule oral argument as soon as possible.

Dated: October 26, 2000

JAMES J. BROSNAHAN
ANNETTE P. CARNEGIE
JOHN H. QUINN
MORRISON & FOERSTER LLP

By: /s/ John H. Quinn
John H. Quinn

Attorneys for Defendants
OAKLAND CANNABIS BUYERS'
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PROOF OF SERVICE BY FACSIMILE TRANSMISSION

I declare that I am employed with the law firm of Morrison & Foerster LLP, whose address is 425 Market Street, San Francisco, California, 94105; I am not a party to the within cause; I am over the age of eighteen years; and that the document described below was transmitted by facsimile transmission to a facsimile machine maintained by the person on whom it is served at the facsimile machine telephone number as last given by that person on any document which he or she has filed in the cause.

I further declare that on the date hereof I served a copy of:

APPELLEES' MOTION TO EXPEDITE APPEAL

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Dana J. Martin, Esq.
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I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed at San Francisco, California, this 26th day of October, 2000.

Margarita Colin	/s/ Margarita Colin
(typed)	(signature)

PROOF OF SERVICE BY MAIL
(FRAP 25(d))

I am employed with the law firm of Morrison & Foerster LLP, whose address is 425 Market Street, San Francisco, California, 95105; I am not a party to the within cause; I am over the age of eighteen years and I am readily familiar with Morrison & Foerster's practice for collection and processing of correspondence for mailing with the United States Postal Service and know that in the ordinary course of Morrison & Foerster's business practice the document described below will be deposited with the United States Postal Service on the same date that it is placed at Morrison & Foerster with postage thereon fully prepaid for collection and mailing.

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APPELLEE'S MOTION TO EXPEDITE APPEAL

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(4)

No. 00-151

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

SETH P. WAXMAN
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REPLY BRIEF FOR THE PETITIONER

The Ninth Circuit has held that medical necessity is a "legally cognizable defense" to a charge of distributing marijuana, a Schedule I controlled substance, in violation of the Controlled Substance Act (CSA), and that district courts have "equitable discretion" to permit an organization to engage in the ongoing distribution of marijuana, wholly outside the Act's strict controls, to individuals claiming a medical need for the drug. Pet App. 8a, 10a. Those unprecedented holdings are fundamentally wrong and warrant review.

1. a. As we demonstrate in our certiorari petition (at 18-20), the court of appeals' decision warrants this Court's review because it significantly undermines the effectiveness of the CSA and threatens the government's ability to enforce an Act of Congress that is central to combating illicit drug trafficking. By listing marijuana as a Schedule I controlled substance, Congress has categorically banned the distribution of marijuana for any purpose, including purported medical use, "[e]xcept as authorized" by the Act itself, 21 U.S.C. 841(a)(1)—*i.e.*, unless the distributor is registered with the DEA and is conducting research approved by the FDA. 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100.(b). That categorical ban may be modified only if the Attorney General, after following the exclusive procedures set forth in the CSA, transfers marijuana from Schedule I to another schedule, or removes marijuana altogether from the CSA. See 21 U.S.C. 811, 812, 829.

The Ninth Circuit's decision flouts those provisions, and goes even further by permitting the open and notorious distribution of marijuana wholly outside the Act's stringent controls, which mandate that *any* person who dispenses *any* controlled substance—even substances listed in Schedules II through V—must register with the DEA, establish security controls, and comply with record-keeping, reporting, order-form, and prescription requirements. See 21 U.S.C. 821-829.

And, finally, the Ninth Circuit's decision places no limitation whatsoever on the quantity of marijuana that respondent or others similarly situated may distribute, either in the aggregate or to particular customers, or the number of people to whom respondents and others may distribute marijuana under the guise of "medical necessity." The decision thus has enormous legal and practical importance.

b. In opposing certiorari, respondents argue (Br. in Opp. 8-13) that the legal issues involved will not be ripe for this Court's review until the Ninth Circuit has disposed of the government's appeal of the district court's July 17, 2000, orders on remand, which modified the district court's May 19, 1998, injunction to permit respondents to distribute marijuana to persons claiming a medical necessity for the drug. Pet. App. 12a-17a.[1] As we explain in the certiorari petition (at 22-23), however, no further factual development or proceedings are needed for this Court to render a definitive resolution of the case. Our petition presents the purely legal question whether the CSA forecloses a medical necessity defense to a violation of the Act. Pet. i. Contrary to petitioner's contention (Br. in Opp. 12), the Ninth Circuit did not address that issue "only indirectly and tangentially." Rather, it held that (1) medical necessity is a "legally cognizable defense" under the Act, Pet. App. 8a, and that (2) a supposed "public interest" in the availability of marijuana for asserted medical uses outweighs the government's "general interest in enforcing" the CSA, *id.* at 9a, 11a. There is no reason to believe that the same Ninth Circuit panel, which has retained jurisdiction over any appeal, *id.* at 11a, will

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[1] Although respondents have requested that the Ninth Circuit expedite its resolution of the government's appeal (Br. in Opp. 2), the court has neither acted on that request nor indicated when it will issue its decision.

revisit those conclusions.[2] Indeed, that court has already determined that "[t]he evidence in the record [on the first appeal] is sufficient to justify the requested modification," and that it had "no doubt" the district court could have modified the injunction on the basis of that evidence had it chosen to do so. *Id.* at 10a.

Contrary to respondents' contention (Br. in Opp. 8), there is no reason to postpone review to allow the Ninth Circuit to consider "new evidence" that patients have a medical need for marijuana or that the City of Oakland has declared that there is a "medical emergency" for marijuana. Those assertions were before the court of appeals when it rendered the decision we seek to have reviewed. Pet. App. 10a. In addition, those assertions ignore the statutory framework of the CSA, which assigns to the Secretary of Health and Human Services and the Attorney General the responsibility to review any evidence concerning the possible efficacy and potential for abuse of controlled substances in order to determine, on a uniform nationwide basis, whether they may be distributed for medical purposes (if approved by the

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[2] Respondents err in asserting (Br. in Opp. 11) that the Ninth Circuit's holding could be supported on the alternative grounds that marijuana distribution is required by substantive due process and Ninth and Tenth Amendment principles. No court has adopted any of those highly dubious contentions, and unless and until a court does so, the decision below has the precedential effect of authorizing marijuana distribution in flagrant violation of the CSA. There is also no merit to respondents' attempt (*id.* at 10) to bring themselves within the immunity for state or local "officers" of a subdivision of a State "who shall be lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances." 21 U.S.C. 885(d). Even if we assume, *arguendo*, that a private organization would qualify as a public "officer," the immunity in Section 885(d), which is designed to permit undercover activities and similar measures to enforce *prohibitions* against the distribution of controlled substances, obviously does not apply to an entity that is engaged in the open and notorious distribution of marijuana with no purpose of enforcing any such prohibitions.

FDA under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, for those purposes). The CSA does not delegate that responsibility to individual district courts, municipal governments, and private distributors of controlled substances throughout the country.

For the foregoing reasons, there is simply nothing to be gained by postponing review of the court of appeals' decision until that court rules on the government's appeal. To the contrary, postponing review would only exacerbate the adverse consequences of the decision by encouraging broad disregard of the CSA and the unregulated distribution of marijuana, with the attendant serious potential for abuse that Congress sought to prevent by placing marijuana in Schedule I under the Act.[3]

Respondents argue (Br. in Opp. 10) that the government would "suffer[] no inconvenience" from a denial of certiorari because this Court, on August 29, 2000, granted our application for a stay of the district court's July 17, 2000, orders on remand. The July 17 orders, however, apply only to *respondents'* distribution of marijuana. The Ninth Circuit's decision recognizing a medical necessity defense has precedential effect throughout the Ninth Circuit, which has a population of more than 50 million people.

Five States in the Ninth Circuit (Alaska, California, Hawaii, Oregon, and Washington) have passed legislation sanctioning the use of marijuana for medicinal purposes. Pet. 20-21. Within those five States, there already are more

---

[3] Respondents contend (Br. in Opp. 7) that the government "remains free * * * to prosecute anyone that it believes to be violating the federal drug laws." But respondents do not dispute that the court of appeals held that "medical necessity" is a "legally cognizable defense" to a criminal prosecution under the CSA. Pet. App. 8a. The recognition of a medical necessity defense therefore would introduce illegitimate collateral issues into drug prosecutions under the Act and would consume unnecessary judicial resources by distracting the trier of fact from the core issues of guilt or innocence of a particular crime as defined by Congress in the CSA.

than two dozen organizations that are engaged in the distribution of marijuana to individuals who claim a need for the drug. See Jean Merl, *Marijuana Distribution Ban Alarms Patients*, Los Angeles Times, Aug. 31, 2000, at B1 (The Supreme Court's stay "order is unlikely to have much immediate effect on the other [24] cannabis clubs around the state."); Martin Kasindorf, *Medicinal Pot Use Set Back*, USA Today, Aug. 30, 2000, at 1A (The Court's stay "order sends a non-binding but chilling message to 35 other clubs currently supplying medicinal marijuana to 20,000 Californians.").[4] Thus, unless and until this Court grants review and reverses the Ninth Circuit's legal rulings, the government will be significantly hampered in enforcing the CSA against drug traffickers who are acting under the guise of "medical necessity." The Court therefore should grant certiorari now so that the matter can be put to rest this Term.

2. Respondents' defense of the court of appeals' decision is equally without merit.

a. Respondents argue (Br. in Opp. 17-29) that neither the CSA nor its history evinces a clear intent to abrogate a common law defense of medical necessity or to divest district courts of their equitable discretion to authorize the distribution of marijuana to those with asserted medical needs. Thus, respondents argue (*id.* at 26, 28) that, whereas Congress placed marijuana in Schedule I in order to restrict its distribution to the "general public," a medical necessity de-

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[4] See also, *e.g.* Holly J. Wolcott, *Marijuana Club Members Support Four Arrested Activists*, Los Angeles Times, Aug. 9, 2000, at B6 (discussing 800 members in Los Angeles Cannabis Resource Center); Ulysses Torassa, *City's Pot Clubs Live On*, San Francisco Examiner, June 13, 1999, at D1 (discussing more than 1000 members in ACT UP San Francisco dispensary; more than 300 members in Market Street Club; more than 600 members in Patients and Caregivers Health Center; and ongoing operations of Cannabis Helping Alleviate Medical Problems (CHAMP)).

fense serves the "different purpose[]" of permitting individuals to smoke marijuana when they and their physicians "jointly agree" that "generally accepted treatments are ineffective." Those assertions are fundamentally mistaken.

As we have explained (Pet. 8-16), the recognition of a medical necessity defense cannot be reconciled with the text and structure of the CSA, or with its overriding purpose to protect the public health and safety from the unauthorized distribution of controlled substances. The CSA regulates marijuana as a "drug." See 21 U.S.C. 802(6), 812. Absent the federal drug laws, there would be no prohibition under federal law against the distribution of marijuana for use by the general public, including by individuals who want to smoke marijuana for a claimed medical purpose. By listing marijuana as a Schedule I controlled substance, however, Congress has determined that marijuana has a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).[5]

Respondents attempt to avoid the plain import of those provisions by asserting (Br. in Opp. 6, 21, 25-29) that the terms "currently accepted medical use in treatment" and "medical necessity" convey different concepts, and that as

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[5] Respondents are wrong in contending (Br. in Opp. 18, 19) that Congress placed marijuana only "tentatively" in Schedule I because it knew that medical experts had not universally concluded that marijuana should be banned for all purposes. Absent rescheduling under the Act, Congress *definitively* has placed marijuana in Schedule I, where it has been listed for 30 years, knowing full well that it was banning the distribution of marijuana for any purpose, including asserted medicinal ones, except as authorized by the CSA. See 116 Cong. Rec. 1664 (1970) (statement of Sen. Hruska) (noting that marijuana was placed on Schedule I because it "comes squarely within the criteria of that schedule," *i.e.*, "highest abuse potential" and "little or no accepted medical use in this country").

long as the Ninth Circuit did not authorize respondents to distribute marijuana to the general public, the court was free to permit them to distribute marijuana to a more limited class of persons, *i.e.*, those who claim a medical need to smoke marijuana. But it is precisely because Congress has determined that marijuana has "*no* currently accepted medical use in treatment" (emphasis added) and placed marijuana in Schedule I that Congress has foreclosed a distributor from violating the CSA on the ground that the recipients claim a "medical necessity" for the drug.

In particular, respondents have not grasped the central point that the CSA imposes an absolute ban on the distribution of marijuana—*including* any distribution for asserted medical purposes—outside the strict confines of the Act itself. 21 U.S.C. 811-812, 823(f), 841(a)(1). Even for drugs listed in Schedules II through V, which Congress and the Attorney General have determined *do* have a "currently accepted medical use," 21 U.S.C. 812(b)(2)-(5), and for which the CSA *does* permit physicians to determine whether particular patients have a medical need, 21 U.S.C. 829, the CSA imposes strict controls on physicians and pharmacies before they may distribute the drug for medical use. See 21 U.S.C. 821-829; 21 C.F.R. Pts. 1301-1306. That comprehensive set of *statutory* controls leaves no room for the distribution of marijuana for medical purposes by relying on a *common law* defense of necessity.[6]

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[6] Respondents erroneously argue (Br. in Opp. 23-26) that, under the rule of lenity, Congress may not foreclose a common law defense of medical necessity without specifically mentioning that defense in the CSA. A necessity defense is unavailable when, as here, it fatally clashes with the text, structure, and purpose of the statute, whether or not Congress expressly has referred to the defense. *United States* v. *Bailey*, 444 U.S. 394, 415-416 & n.11 (1980) (declining to apply necessity defense in a manner that would render a congressional judgment "wholly nugatory"); see also Model Penal Code § 3.02(1)(c) (1962) (defense available only where

The Ninth Circuit's decision abandons even any pretext of compliance with those provisions and instead relegates to district courts and juries the power to determine whether illicit drugs can be distributed for an asserted medical use. The Ninth Circuit's recognition of a medical necessity defense also cannot be reconciled with Congress's unambiguous expression in the 1998 legislation, passed in specific response to efforts in some States to legalize the use of marijuana for medical purposes (see Pet. 11-12), of its continued adherence to the rule that the use of marijuana for asserted medical purposes not be permitted "without valid scientific evidence and the approval of the Food and Drug Administration." Act of Oct. 21, 1998, Pub. L. No. 105-277, Div. F, 112 Stat. 2681-2761.[7] And the Ninth Circuit's decision likewise cannot be squared with *United States* v. *Rutherford*, 442 U.S. 544 (1979), in which this Court unanimously rejected the assertion that the safety and effectiveness standards of the FDCA had no application to terminally ill cancer patients, reasoning that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is incumbent upon the courts to give it effect. 442 U.S. at 551.

b. Respondents contend (Br. in Opp. 13-17) that, under this Court's decisions in *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305 (1982), and *Hecht Co.* v. *Bowles*, 321 U.S. 321

"a legislative purpose to exclude the justification claimed does not otherwise plainly appear"); see also Pet. 8-9.

[7] Respondents argue (Br. in Opp. 20) that the 1998 Act "does not have the force of law." Respondents ignore the fact that the CSA (and the FDCA) *already* bar the distribution of marijuana. The 1998 Act expressly confirms those preexisting prohibitions specifically with respect to the use of marijuana for asserted medical purposes, and it therefore also refutes the notion that a court may allow the distribution of marijuana based on its own view of the "public interest." The authorities cited by respondent do not cast doubt on the significance of the 1998 Act in those respects.

(1944), district courts have the equitable discretion to decline to enjoin conduct that indisputably violates federal law. Neither decision, however, supports that proposition.

As we have explained (Pet. 17-18), district courts sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937); see also *Miller* v. *French*, 120 S. Ct. 2246, 2253 (2000); *TVA* v. *Hill*, 437 U.S. 153, 194 (1978). The decisions in *Romero-Barcelo* and *Hecht Co.* strongly support our position that a court may not exercise its equitable discretion—which is intended to allow a court to decide how best to assure *compliance* with the Act—so as to countenance ongoing *violations* of the Act.

In *Romero-Barcelo*, the Court held that under the Federal Water Pollution Control Act, the district court retained discretion to order relief, other than an immediate injunction, that would "achieve compliance" with the statute. 456 U.S. at 307. The district court found that the Navy had committed "technical violations" of the statute, without "causing any 'appreciable harm' to the environment," by occasionally discharging ordnance into waters without a permit. *Id.* at 310. The Supreme Court found that "although the District Court declined to enjoin the discharges, it neither ignored the statutory violation nor undercut the purpose and function of the permit system." *Id.* at 315. The Court further observed that, "[r]ather than requiring a district court to issue an injunction for any and all statutory violations, the FWPCA permits the district court to order that relief it considers necessary *to secure prompt compliance with the Act.*" *Id.* at 320 (emphasis added).

Similarly, in *Hecht Co.*, the district court declined the government's request for an injunction against a defendant that had violated statutory price controls. The district court reasoned that it had "no doubt" that the defendant acted in "good faith and diligence" in attempting to comply with statute, that it had taken "vigorous steps" to correct and

prevent recurrence of its mistakes, and that issuance of an injunction would have "no effect" on ensuring future compliance. 321 U.S. at 325, 326. This Court concluded that under the statute "there is some room for the exercise of discretion on the part of the court," and that other remedial orders short of an injunction might have been consistent with the statute. *Id.* at 328. The Court made clear, however, that courts had the responsibility to enforce the statute and that "their discretion under [the statute] must be exercised in light of the large objectives of the Act." *Id.* at 331.

Those decisions stand in stark contrast to the Ninth Circuit's ruling here, which allows the ongoing distribution of marijuana in open violation of the CSA. Congress itself has weighed what it deemed to be the relevant public-interest considerations and made the fundamental policy choice that "the illegal * * * distribution[] and * * * improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. 801(2), and therefore that marijuana, a Schedule I controlled substance, may not be distributed for any purpose, "[e]xcept as authorized" by the Act, 21 U.S.C. 841(a)(1). Accordingly, the Ninth Circuit's extraordinary holding that a court may allow the distribution of marijuana notwithstanding the CSA is clearly contrary to the Act and warrants this Court's review.

* * * * *

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General

NOVEMBER 2000

(5)

Supreme Court, U.S.
FILED
JAN 11 2001
OFFICE OF THE CLERK

No. 00-151

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

JOINT APPENDIX

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PETITION FOR WRIT OF CERTIORARI FILED: JULY 28, 2000
CERTIORARI GRANTED: NOVEMBER 27, 2000

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* These materials were introduced by respondents in the district court on May 30, 2000, in support of respondents' motion to modify or dissolve preliminary injunction, following the Ninth Circuit's September 13, 1999 decision.

** These declarations were introduced in the district court by respondents on September 14, 1998, as attached to respondents' request for judicial notice, which the district court never acted upon.

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00089 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OF LAURA A. GALLI, R.N.

I, LAURA A. GALLI, declare:

1. I am one of two registered nurses who work at the Oakland Cannabis Buyers' Cooperative (the "Cooperative" or "OCBC"). As a staff nurse I am familiar with the policies and procedures of the OCBC. I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. From 1990 through 1992 I worked as a student nurse intern and unit secretary in the Rehabilitation Unit at Mills-Peninsula Hospitals. During that time I

studied for my nursing degree at Cal-State Hayward, which degree I received in 1992. However, in July 1992 I was diagnosed with pleurisy and with lupus. This medical condition prevented me from being able to continue employment as a nurse. Currently I am an "inactive" registered nurse.

3. I work as a volunteer at the Cooperative as a staff nurse. The Intake Department of the Cooperative includes two staff nurses, one of whom is always on duty while the Cooperative is open on weekdays.

4. Before a patient is accepted for membership into the Cooperative, he or she must complete an extensive screening process. This process is described in detail in the Oakland Cannabis Buyers' Cooperative Protocols ("Protocols"), a copy of which is attached hereto as Exhibit 1. Before reaching my office, all applicants must satisfy the threshold requirement of providing authorization from a treating physician assenting to cannabis therapy for one or more medical conditions listed on the Medicinal Cannabis User Initial Questionnaire (Exhibit C to the Protocols).

5. If, upon screening by the Cooperative Intake staff member, the applicant cannot provide such authorization, he or she will be denied membership to the Cooperative.

6. Once the applicant provides a doctor's authorization for medical cannabis, it is my job to independently verify the physician's approval. No applicant is admitted to membership to the Cooperative unless and until I or the other staff nurse verify the applicant's physician's approval.

7. For each and every Cooperative applicant, either I or the other staff nurse telephone the applicant's doctor's office to verify the authenticity of the authorization submitted by the prospective member. I talk with the doctor (or in some instances a member of the doctor's staff) to confirm that the doctor did in fact authorize the use of cannabis for a medical condition. I also will confirm the date of the authorization. If the doctor or his staff cannot provide satisfactory responses to my questions, then I screen out the Cooperative applicant and reject the applicant for membership. A copy of the Verification of Physician's Written Recommendation form that I use is attached hereto as Exhibit 2.

8. For each and every doctor who has authorized the use of medical cannabis to one of the Cooperative applicants, either I or the other staff nurse confirm that the doctor is licensed to practice medicine in the State of California. If the doctor's credentials cannot be confirmed, then I reject the applicant for membership.

9. Soon after an applicant is admitted to membership in the Cooperative, he or she is issued a laminated membership card. A copy of a membership card is attached as Exhibit J to the Protocols. Each time a patient-member comes to the Cooperative, he or she must present this membership card along with secondary valid photo identification in order to gain entry.

10. I am familiar with the range of medical conditions from which the Cooperative's patient-members suffer. Patient-members of the Cooperative suffer from debilitating and often deadly diseases, including HIV and/or AIDS, cancer, arthritis, multiple sclerosis, and glaucoma. I know that medical cannabis provides relief

to patient-members as a pain reliever, an appetite stimulant, an anti-nauseant, and an anti-convulsant. Medical cannabis also relieves intraocular eye pressure in patient-members who suffer from glaucoma.

11. Although every patient's experience is unique, some general comments apply to many patients. For some Cooperative members, they have tried other legal medicines to alleviate their conditions but these other medicines do not work for them. For other members, other drugs have intolerable negative side effects which they have chosen not to endure. Some members' experiences with other legal medicines is that, while they are somewhat effective, they are not nearly as effective at relieving their symptoms as medical cannabis.

12. I have seen patient-members who suffer from AIDS-related "wasting syndrome" as well as those who have cancer and are undergoing chemotherapy and radiation therapy. Medical cannabis reduces nausea and increases appetite in these patients. Other medicines either do not work for some of these patients or they have serious adverse side effects that cannabis does not have. Supplying medical cannabis to these patient-members is necessary to avert imminent and potentially life-threatening harm.

13. I have also seen patient-members who suffer from multiple sclerosis or quadriplegia. They experience debilitating spasticity and/or constant pain. Other medicines simply do not work for many of these patient-members. These patients can also experience intolerable adverse side effects from other medications —side effects that cannabis does not have.

14. I suffer from both lupus and fibromyalgia. Lupus is a disease of the immune system which, among other things, causes an arthritic-type condition and arthritis-type pain. Fibromyalgia is a pain syndrome which affects the ligaments and tendons in all of my joints. I live in nearly-constant pain.

15. There are many medications I must take to treat my conditions. These medications have many adverse side effects, including stomach upset, chronic nausea and vomiting, and they can be addictive.

16. The doctors are not sure why I experience chronic nausea and vomiting. Over the years I have tried many medications and treatments to try to alleviate my nausea symptoms, but nothing worked for me.

17. Eventually, my primary care physician—Dr. Richard Morgan— authorized medical cannabis for my nausea and reduced appetite. This medicine has worked wonders for me. It has relieved my nausea and increased my appetite when nothing else would. Medical cannabis has had the additional benefit of helping to reduce my pain.

18. If I were forced to go without cannabis now I would be a mess—I would again have no appetite and would lose weight, I would experience a dramatic increase in nausea and vomiting, and the pain in my joints would increase. If the OCBC were forced to close down, I would in turn be forced to obtain cannabis on the criminal market. But at this point I would not know where to begin to look for cannabis. Resorting to the criminal market would make me seriously nervous for my safety.

19. In fact, many other patient-members' lives may be endangered if they were forced to try to obtain cannabis from criminal street dealers. This is in part because impurities in marijuana purchased on the street may be harmful to their health. It is also because it would be very dangerous for many of our patient-members to enter a high crime area which is where they would have to go to obtain cannabis. Some patient-members may choose to forego their medication if they have no choice but to turn to street dealers for cannabis.

20. The Cooperative, by contrast, provides a safe environment for patient-members to obtain their much needed medicine.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 12th day of September at Oakland, California.

/s/ LAURA A. GALLI, R.N.
LAURA A. GALLI, R.N.

EXHIBIT 1

Oakland Cannabis Buyers' Cooperative

Protocols

[Seal Omitted]

Compassion

Oakland Cannabis Buyers' Cooperative
Post Office Box 70401
Oakland, California 94612-0401
Tel. 510-832-5346
Fax 510-986-0534
Email ocbc@rxcbc.org
Web www.rxcbc.org

March 30 1998

Oakland Cannabis Buyers' Cooperative

Protocols

The Oakland Cannabis Buyers' Cooperative operates pursuant to and in accordance with the statewide mandate of Proposition 215 (Exhibit A) and Resolutions passed unanimously by the Oakland City Council and an Administrative Memorandum promulgated by the Chief of Police (Exhibit B). Its operating procedures have been consolidated as these Protocols.

I. Admission and Membership Requirements

A person seeking membership of the Oakland Cannabis Buyers' Cooperative must at the threshold provide a note from a treating physician assenting to cannabis therapy for a medical condition listed on the Medicinal Cannabis User Initial Questionnaire (Exhibit C). Upon acceptance of the note by Intake staff, the prospective member will undergo an extensive screening and such questioning as shall establish that the candidate meets the Medical Admissions Criteria (Exhibit D) including, without being limited to, the Oakland Cannabis Buyers' Cooperative Information Form (Exhibit E). If, upon the screening by Cooperative staff the candidate does not appear to qualify for membership, he or she will be denied membership with a statement of reasons for his/her being screened out. If the candidate appears to qualify for membership, Intake staff will give the candidate the Authorization for Release of Patient Status form (Exhibit F) and the Physician Statement (Exhibit G), with a request that the candidate's treating physician sign it. When the form is returned, the Intake staff will verify the physician's approval by independent telephone verification. Medical cannabis

cultivators and manufactures are issued cultivation and manufacturing Certificates (Exhibit H), which the City Council has approved to aid the Police in recognizing agents of the Cooperative.

No person under the age of eighteen shall be admitted to membership without the written consent of parents, in addition to meeting all other requirements.

II. Responsibilities of Membership

All members must sign a Membership Agreement (Exhibit 1), whereupon they will receive a Membership Card (Exhibit I). Members agree to conduct themselves discreetly, in accordance with the Statement of Safe Use of Cannabis (Exhibit K) and the Principles of Responsible Cannabis Use (Exhibit L).

III. Other Provisions

A. Purpose. The purpose of the Oakland Cannabis Buyers' Cooperative is to help provide medicine for people who need it. Accordingly, it shall be operated as a not for profit organization.

B. Privacy of members. The staff of the Cooperative shall take steps to protect the privacy and identity of members. However, neither the Cooperative nor its staff shall be liable for any breach thereof

C. Changes. These Protocols, and all medical protocols, are subject to change without notice from time to time in the sole discretion of management.

D. Cooperative operation.

a. No smoking of anything on premises.

b. Members shall observe additional house rules as same maybe posted by management.
c. Management may eject any person at any time.

Exhibits

A. Proposition 215

B. Oakland City Council Resolutions and Police Memorandum

C. Medicinal Cannabis User Initial Questionnaire

D. Medical Admissions Criteria

E. Information Form

F. Authorization for Release of Patient Status

G. Physician Statement

H. Cultivation and Manufacturing Certificates

I. Membership Agreement

J. Membership Card

K. Statement of Safe Use of Cannabis

L. Principles of Responsible Cannabis Use

Ex. E

OAKLAND CANNABIS BUYERS' COOPERATIVE

INFORMATION FORM [Seal Omitted]
(Please print clearly)

Compassion

Name_____

Street Address_____Apt. Number_____

City _____,State _____Zip Code_____

Phone Number (___) _____Date of Birth_____

Driver License #____State__Gender (M or F) _____

Caregiver _____DL# _____DOB_____

Physician's Name_____DX # _____

Address, City, State_____PHD# _____

Phone (_____) _____

Specific Diagnosis _____

_____ICD9 CODE_____

Medication(s)_____

_____

How do you use cannabis? Smoke hi grade_____
smoke lo grade_____edibles_____tinture_____

Are you politically active? _____

Member Signature	Date
Intake By	Member #

OAKLAND CANNABIS BUYERS' COOPERATIVE, P.O. Box 70401
Oakland, CA 94612-0401
Phone (510) 832-5346 Fax (510) 986-0534
Email ocbc@rxcbc.org Web www.rxcbc.org

Ex. F

OAKLAND CANNABIS BUYERS' COOPERATIVE

[Seal Omitted]

Authorization for Release of Patient Status
(Please print clearly)

Compassion

I,_____hereby authorize my treating
print patient name
physician, Dr._____to release to the
print patient name
Oakland Cannabis Buyers' Cooperative, my current patient status.

_____Date_____
Member/patient signature

Membership number_____

OAKLAND CANNABIS BUYERS' COOPERATIVE, P.O. Box 70401
Oakland, CA 94612-0401
Phone (510) 832-5346 Fax (510) 986-0534
Email ocbc@rxcbc.org Web www.rxcbc.org

Ex. G

Health and Safety Code 11362.5
PHYSICIAN'S STATEMENT

[Seal Omitted]
Compassion

This certifies that _____ is a patient under
print patient's name
my medical care and supervision for the treatment of _____.
Diagnosis

I have discussed the medical benefits and risks of cannabis use with the patient as a treatment for these medical conditions. I recommend cannabis use for my patient.

If my patient chooses to use cannabis therapeutically, I will continue to monitor his/her medical condition and to provide advice on his/her progress.

I understand that I may be contacted to verify the information in this letter. My patient authorizes me to discuss their medical condition and the contents of this letter, for verification purposes only. I am a physician licensed to practice medicine in the state of California.

_____
Patient's Signature

_____ _____
Physician's Signature Date

_____ _____
Physician's Name (print) N.P./P.A. Signature (optional)

Physician's CA License No.

N.P./P.A. Name (optional-print)

(street)

(City)

( )

Phone Number

Certificate of Membership

This is to certify that on file with the undersigned officer of the Oakland Cannabis Buyers' Cooperative is a signed statement of a licensed Physician acknowledging and assenting to cannabis therapy for the patient identified on the reverse hereof, who, having satisfied all conditions of membership, is recognized as a Member in good standing of the

Oakland Cannabis Buyers' Cooperative

with all benefits and subject to all conditions as same shall from time to time be established by the Oakland CBC in accordance with its rules and Protocols. Presentation of this card shall be evidence that said patient's Physician would consider prescribing cannabis if he/she were legally able to do so, assents to the theraputic use, and has agreed to monitor and provide medical advice on the patient's progress.

Hours:

M & F 11am-7pm T, W, TH 11am-1pm, 5pm-7pm

Office # (510) 832-5346

24 hr Emergency voicemail/ pager service (for Law Enforcement use only) 1-888-340-1260.

_____

JEFFREY W. JONES
Executive Director

Oakland Cannabis
Buyers' Cooperative
[Seal Omitted]
Compassion

OAKLAND CANNABIS BUYERS' COOPERATIVE
Health and Safety Code 11362.5
VERIFICATION OF PHYSICIAN'S WRITTEN RECOMMENDATION

_____ _____

Patient's Name (printed) Membership Number

I have documents stating the physician indicated below attests that:

__He/She is aware of this patient's use of medical cannabis.

__He/She has discussed the risks and benefits of cannabis use with this patient.

__He/She will monitor the use of medical cannabis for this patient.

__He/She recommends or approves the use of medical cannabis for this patient.

OR

He/She recommends <u>against</u> medical cannabis for this patient.

Verification Information was provided by_____ on____ at____

__ Office staff at physician's phone number

__ Direct discussion with physician

__ Nurse at physician's phone number

__Nurse practitioner or physician's assistant at physician's phone number

---

Physician's Name	Date seen by Physician
Address	M.D. Specified Expiration Date (optional)
	CA License No. (obtain by phone)
( ) Phone	License Expiration Date
ICD9 Code	

I have verified this physician's California License as current and valid by checking with the California Board of Medical Quality Assurance. Date verified:_____

Employee's Name	Employee's Signature

OAKLAND CANNABIS BUYERS' COOPERATIVE, P. O Box 70401
Oakland, CA 94612-0401
Phone (510) 832-5346 Fax (510) 986-0534
Email ocbc@rxobc.org Web www.rxobc.org

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

[Filed: Sept. 30, 1998]

AMENDED DECLARATION OF
MICHAEL M. ALCALAY, M.D., M.P.H.

I, MICHAEL M. ALCALAY, declare:

1. I am Medical Director of the Oakland Cannabis Buyers' Cooperative (the "Cooperative" or "OCBC"). As Medical Director I am familiar with the policies and procedures of the OCBC. I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. I am a Board-certified pediatrician. I graduated from U.C.L.A. medical school in 1968. I received a Masters Degree in public health in 1973 from the University of California Berkeley School of Public Health. I practiced as a pediatrician in the Northern California Kaiser Hospitals until 1995 when I became ill.

3. In addition to my work as a physician, from 1987 through 1993, I was also an award winning producer of a nationally syndicated weekly medical program entitled "AIDS in Focus".

4. As Medical Director of the Cooperative I attend regular board meetings and consortium meetings. Other duties include acting as liaison between the Cooperative and patient-members' authorizing physicians. As a result of my duties as Medical Director, I am knowledgeable about many Cooperative patients and their medical conditions. On May 21, 1998, I was present at the Cooperative at the time of the scheduled press conference.

5. I am also a patient-member of the Cooperative. I learned I was HIV-positive in 1986. I was first diagnosed with AIDS in 1993. In 1995, I became very seriously ill with an AIDS-related condition called cryptosporidium. I contracted this disease from drinking the local water supply. Cryptosporidium caused me to have constant diarrhea, I experienced a dramatic loss of my appetite, and I also suffered generally from apathy. I rapidly lost thirty pounds as I dropped from weighing 165 pounds to 135 pounds. At one point visiting nurses came regularly to my home so that I could be fed intravenously. I was suffering from the classic "wasting syndrome" that is associated with many AIDS patients.

6. When I eventually medicated myself with cannabis, I regained my appetite, and I was finally able to regain weight again. The cannabis kept me alive until a therapy could be found to eradicate the microbe from my body. The cannabis also caused a dramatic improvement in my spirits. I have since recovered from a very serious and life-threatening illness.

7. I have been required to take a lot of different medications to treat my AIDS condition, including the drug AZT and a variety of different protease inhibitors. I need these medications in order to live. But these medicines cause nausea and vomiting. To combat the nausea I have tried several prescription drugs including Marinol and Atarax, but none of them have worked for me. Marinol did not work well for me at all because it was nearly impossible to time its effect or to achieve the right dosage. It would take up to an hour or more to take effect, and I had trouble finding the correct dosage as a result of this long lag time in its kicking in. Atarax was not as effective as cannabis in alleviating my nausea.

8. Cannabis has been the only medicine that has worked for me to control the nausea and vomiting caused by my AIDS medications. It starts to provide relief after only a few minutes of inhaling just a little bit.

9. The goal of the Cooperative is to provide seriously ill patients with a safe and reliable source of medical cannabis products and plants. The Cooperative is open to all patients with a verifiable letter of diagnosis and recommendation or approval from a doctor for medical cannabis use. A complete Mission Statement is

attached to the Declaration of James D. McClelland as Exhibit 1.

10. The Cooperative consists of one class of patient-members. According to the Cooperative's Bylaws, to qualify for membership an applicant must comply with the Protocols of the Oakland Cannabis Buyers' Cooperative. A copy of the OCBC Bylaws and Articles of Incorporation is attached to the Declaration of James D. McClelland as Exhibit 2.

11. Before a patient is accepted for membership into the Cooperative, he or she must complete an extensive screening process. This process is described in detail in the Oakland Cannabis Buyers' Cooperative Protocols ("Protocols"), a copy of which is attached to the Declaration of James D. McClelland as Exhibit 3.

12. According to the stated policies and procedures of the Cooperative, all applicants first must satisfy the threshold requirement of providing authorization from a treating physician assenting to cannabis therapy for one or more medical conditions listed on the Medicinal Cannabis User Initial Questionnaire (Exhibit C to the Protocols). Upon acceptance of the doctor's note by Intake staff, the prospective member undergoes an extensive screening process to determine whether the applicant meets the Medical Admissions Criteria (Exhibit D to the Protocols). Each applicant must fill out and submit the Cooperative Information Form (Exhibit E to the Protocols).

13. If, upon screening by the Cooperative Intake staff member the applicant does not qualify for membership, he or she will be denied membership to the Cooperative.

14. If the applicant does appear to qualify for membership, a staff nurse must independently verify the physician's approval of cannabis use. It is the OCBC's policy and practice that an applicant not be admitted to membership in the Cooperative unless and until the applicant's physician's approval is verified by the staff nurse.

15. The Cooperative schedules a staff nurse to be on duty throughout every weekday business hour of the Cooperative.

16. Shortly after an applicant is admitted to membership in the Cooperative, he or she is issued a laminated membership card. A copy of a membership card is attached as Exhibit J to the Protocols. Each time a patient-member comes to the Cooperative he or she must present this membership card along with secondary valid photo identification.

17. Each time a patient-member comes to the Cooperative to receive medicine, the patient-member must pass three separate security check-points. At each of the check-points the member must present two forms of identification described in paragraph 17. First, the member must present identification to a security guard at the front door to the Cooperative. Second, a second security guard examines the member's identification at the member room door leading into the sales area of the Cooperative. Finally, a Cooperative staff member always checks the patient-member's identification again at the point of sale.

18. I am personally aware that patient-members of the Cooperative suffer from debilitating and often deadly diseases, including HIV and/or AIDS, cancer,

arthritis, multiple sclerosis, and glaucoma—to name a few. I have seen and am aware that medical cannabis provides relief to patient-members as a pain reliever, an appetite stimulant, an anti-nauseant, and as relief from spasticity. Medical cannabis relieves intraocular eye pressure in patient-members who suffer from glaucoma.

19. As Medical Director, I have reviewed and am generally familiar with the medical circumstances that have led Cooperative members to seek medical cannabis. Although every patient's experience is unique, some general comments apply to many patients. Some Cooperative members have tried other legal medications to alleviate their conditions, but these other medications do not work for them. For other members, other medications have intolerable negative side effects they have chosen not to endure. Some members' experiences with other legal medications is that, while they are somewhat effective, they are not nearly as effective at relieving their symptoms as medical cannabis.

20. I am aware that Cooperative patient-members suffering from AIDS-related "wasting syndrome" (including myself) and those with cancer undergoing chemotherapy experience nausea and severe appetite deficits. Patients such as myself suffer these same conditions also as a result of having to take multiple medications to treat AIDS, some of them new or experimental. I am aware that medical cannabis relieves these symptoms in patients and enables them to eat. Medical cannabis prolongs some of these patients' lives (including my own). Cannabis enables these patients to take the other medications (in the case of AIDS

patients) or to continue to undergo the intensive chemotherapy (in the case of cancer patients) in order to stay alive. For these patients, other medicines either do not work at all (or they are not nearly as effective as medical cannabis) or they cause severe adverse side effects that medical cannabis does not cause. I believe, based on personal experience, that supplying medical cannabis to these patient-members is necessary to avert imminent and often life-threatening harm.

21. I am aware that the patient-members who suffer from multiple sclerosis or quadriplegia experience debilitating spasticity and/or constant pain. Unless medicated these patients will be forced to live with uncontrollable muscular spasticity or to endure debilitating pain throughout every day. For many of these patients, other medications or treatments either do not work at all, they are not nearly as effective as medical cannabis, or they cause severe adverse side effects that medical cannabis does not cause. Thus, many of these patient-members have no reasonable alternative to medical cannabis.

22. On May 21, 1998, approximately 191 patients came to the Cooperative. Sixty-six percent of the patients who came to the Cooperative suffered from HIV and/or AIDS, 4 % of patients who came to the Cooperative suffered from cancer, 2 % of patients who came to the Cooperative suffered from glaucoma, 1 % of patients who came to the Cooperative suffered from multiple sclerosis, and almost 20 % of patients who came to the Cooperative suffered from disorders involving chronic pain, such as quadriplegia.

23. For each and every patient-member who came to the Cooperative on May 21, 1998, there exists in the

OCBC files written confirmation that a treating California physician acknowledged and assented to cannabis therapy to treat the patient's medical condition or conditions.

24. The OCBC maintains, in the normal course of business, a database which contains information concerning its patient-members, including their diagnosis. I am familiar with the manner in which this information is gathered and entered into the database. Intake workers and volunteers who are qualified to do so, review documents in the patient's file, including personal information provided by the patient, the intake questionnaire containing the patient's diagnosis, and the information confirming that a licensed California doctor has made the diagnosis and has recommended the use of medical cannabis. Information concerning the diagnosis, the IC-9 (a standardized code used by physicians to classify a patient's medical condition), as well as the patient's name and treating physician are entered into the computer. Attached hereto as Exhibit A is a true and correct copy of a printout from OCBC's database concerning the patients who were present at the Cooperative on May 21, 1998. This printout contains the patient's identification number, the patient's specific diagnosis, and the IC-9 code.

25. Numerous attempts have been made to obtain sworn declarations of patient-members who came to the Cooperative on May 21, 1998. Many of these patients, however, are afraid to sign any declaration as a result of the federal government's announced intention not to immunize any such declarations offered in this proceeding from use in any possible subsequent criminal proceedings. Many of these patients would sign declar-

ations detailing for the Court their medical condition and their dire need of medical cannabis to alleviate their condition if these statements were immunized.

26. One of the patient-members who came to the Cooperative on May 21, 1998, is now deceased. She died from cancer.

27. I have reviewed and am familiar with the medical records and OCBC files relating to the patients who visited the Cooperative on May 21, 1998. Numerous California physicians have rendered a medical opinion approving cannabis treatment for these patients.

28. Many patient-members' lives may be put in jeopardy if they were forced to try to obtain cannabis from criminal street dealers. This is what would happen if the OCBC were forced to close down. They may be placed in danger both because the act of purchasing from street dealers is inherently dangerous and because impurities in marijuana purchased on the street may be harmful to their fragile health. There is also the danger that this method of obtaining cannabis will certainly lead to exposure to dangerous drugs sold on the street, which may in turn lead to temptations or opportunities which have no place at the OCBC. Some patient-members may choose to forego their medication if they have no choice but to turn to street dealers for cannabis.

29. The patient-members of the Cooperative are joint participants in a cooperative effort to obtain and share medical cannabis. Patient-members of the Cooperative jointly acquire marijuana for medical purposes to be shared among themselves and not with anyone

else. No third persons are involved other than "primary caregivers" who are responsible for the housing, health, or safety of the patient. Any payment made to the Cooperative constitutes reimbursement for administrative expenses and operations which all patient-members who utilize the services of the Cooperative agree to share. Attached to the Declaration of James D. McClelland as Exhibit 4 is a true and correct copy of the Oakland Cannabis Buyers' Cooperative Statement Of Conditions under which each and every member agrees to receive his or her medicine.

30. The Cooperative prohibits the smoking of cannabis on its premises; therefore, patient-members who smoke medical cannabis cannot immediately consume their medicine in the presence of other patient-members.

31. Last month, the City of Oakland designated the Oakland Cannabis Buyers' Cooperative to administer the City's Medical Cannabis Distribution Program. Attached to the Declaration of James D. McClelland as Exhibit 5 is a true and correct copy of this designation along with supporting documents which helped satisfy the City of Oakland that the Cooperative is a bona fide corporation safely and lawfully engaged in activities benefiting the citizens of Oakland

32. I understand and believe that currently the federal government will not enroll any additional patients in any federal program studying the medical use of cannabis.

33. I understand and believe that currently pending are petitions to reschedule medical cannabis from Schedule I to Schedule II of the Controlled Substances

Act, but that none of these petitions have yet been granted.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 30th day of September at San Francisco, California.

/s/ MICHAEL M. ALCALAY
MICHAEL M. ALCALAY

EXHIBIT A

Combined Summary

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	2	Carcinoma of Rt. Lung	162.9
5/21/98	7	ARC, Epilepsy, Stress	042.
5/21/98	7	ARC, Epilepsy, Stress	042.
5/21/98	19	HIV	042.
5/21/98	26	HIV	042.
5/21/98	31	HIV	042.
5/21/98	32	Arthritis	716.90
5/21/98	36	AIDS	042.
5/21/98	38	HIV	042.
5/21/98	39	Back pain, Dorsal Kyphosis	732.8
5/21/98	52	Severe Anxiety	300.00
5/21/98	65	AIDS	042.
5/21/98	82	HIV	042.
5/21/98	92	Meniere's Disease	386.0
5/21/98	110	Paranoid Schizophrenia	295.9
5/21/98	124	Cervical Spondylosis	755.9
5/21/98	138	Epididymitis	604.90
5/21/98	139	AIDS	042.
5/21/98	166	AIDS	042.
5/21/98	167	AIDS	042.
5/21/98	167	AIDS	042.
5/21/98	168	HIV	042.
5/21/98	172	AIDS	042.
5/21/98	174	AIDS	042.
5/21/98	175	HIV	042.
5/21/98	177	HIV	042.
5/21/98	186	Paralysis Lower Extremities (Polio)	344.9

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	189	Acute Anxiety, Depression	295.9
5/21/98	190	HIV	042.
5/21/98	193	AIDS	042.
5/21/98	195	AIDS	042.
5/21/98	198	AIDS	042.
5/21/98	207	Bipolar Disorder	296.4
5/21/98	210	AIDS	042.
5/21/98	212	Thyroid Carcinoma	226.
5/21/98	212	Thyroid Carcinoma	226.
5/21/98	213	Scoliosis, Back Pain	737.30
5/21/98	215	Glaucoma	365.9
5/21/98	219	Neuropathy Entrapment	355.9
5/21/98	229	HIV	042.
5/21/98	246	AIDS	042.
5/21/98	248	Glaucoma	365.9
5/21/98	252	AIDS	042.
5/21/98	265	AIDS	042.
5/21/98	284	AIDS	042.
5/21/98	284	AIDS	042.
5/21/98	297	HIV	042.
5/21/98	297	HIV	042.
5/21/98	304	HIV	042.
5/21/98	313	AIDS	042.
5/21/98	317	AIDS	042.
5/21/98	358	AIDS	042.
5/21/98	359	HIV	042.
5/21/98	374	Amputation	897.4
5/21/98	382	HIV	042.
5/21/98	388	HIV	042.
5/21/98	404	AIDS	042.

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	410	Lumbar Strain	-724.0
5/21/98	410	Lumbar Strain	724.0
5/21/98	451	HIV	042.
5/21/98	472	Lung Cancer	162.9
5/21/98	492	AIDS	042.
5/21/98	495	AIDS	042.
5/21/98	502	AIDS	042.
5/21/98	510	AIDS	042.
5/21/98	514	Multiple Sclerosis	340.
5/21/98	565	HIV	042.
5/21/98	571	Multiple Herniated Discs	722.6
5/21/98	578	Hepatitus C, Cerviel DTD Seizure D	715.00
5/21/98	586	AIDS	042.
5/21/98	587	Cluster Migrains	346.10
5/21/98	606	AIDS	042.
5/21/98	620	Neurofibromatosis	237.7
5/21/98	654	AIDS	042.
5/21/98	654	AIDS	042.
5/21/98	654	AIDS	042.
5/21/98	661	HIV	042.
5/21/98	664	HIV	042.
5/21/95	674	AIDS	042.
5/21/98	674	AIDS	042.
5/21/98	677	AIDS	042.
5/21/98	686	HIV	042.
5/21/98	697	AIDS	042.
5/21/98	735	Muscle Spasm, Gastritis	728.85
5/21/98	735	Muscle Spasm, Gastritis	728.85
5/21/98	746	AIDS	042.

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	756	AIDS	042.
5/21/98	759	HIV	042.
5/21/98	763	Glaucoma	365.11
5/21/98	788	Diabetic Neuropathy	250.0
5/21/98	801	Musculoskeletal Hip Pain	729.81
5/21/98	803	AIDS	042.
5/21/98	816	AIDS	042.
5/21/98	826	AIDS	042.
5/21/98	832	HIV	042.
5/21/98	839	HIV	042.
5/21/98	848	Depression	300.4
5/21/98	866	AIDS	042.
5/21/98	871	AIDS	042.
5/21/98	888	AIDS	042.
5/21/98	892	HIV	042.
5/21/98	898	HIV	042.
5/21/98	900	AIDS	042.
5/21/98	901	Multiple Sclerosis	340.
5/21/98	902	AIDS	042.
5/21/98	908	AIDS	042.
5/21/98	940	HIV	042.
5/21/98	966	AIDS	042.
5/21/98	968	AIDS	042.
5/21/98	969	AIDS	042.
5/21/98	972	AIDS	042.
5/21/98	994	AIDS	042.
5/21/98	998	HIV	042.
5/21/98	998	HIV	042.
5/21/98	1003	HIV	042.
5/21/98	1003	HIV	042.

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	1007	AIDS	042.
5/21/98	1027	AIDS	042.
5/21/98	1028	HIV	042.
5/21/98	1031	AIDS	042.
5/21/98	1031	AIDS	042.
5/21/98	1033	AIDS	042.
5/21/98	1035	HIV	042.
5/21/98	1035	HIV	042.
5/21/98	1056	Anxiety Disorder	300.5
5/21/98	1089	Spondylosis Cervical Severe	720.9
5/21/98	1103	Depression	
5/21/98	1123	HIV	042.
5/21/98	1126	AIDS	042.
5/21/98	1128	HIV	042.
5/21/98	1135	Paranoid Schizoophrenio	295.4
5/21/98	1175	AIDS	042.
5/21/98	1195	Arthritis	716.5
5/21/98	1195	Arthritis	716.5
5/21/98	1214	HIV	042.
5/21/98	1215	AIDS	042.
5/21/98	1220	AIDS	042.
5/21/98	1223	AIDS	042.
5/21/98	1233	AIDS	042
5/21/98	1244	Migrane	365.9
5/21/98	1247	Macular Degeneration	362.50
5/21/98	1252	Severe Spinal Strain	729.9
5/21/98	1252	Severe Spinal Strain	729.9
5/21/98	1255	Cancer	
5/21/98	1285	Fibrorhyalia/Depression	
5/21/98	1286	AIDS	042.

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	1289	AIDS	042.
5/21/98	1301	AIDS	042.
5/21/98	1305	AIDS	042.
5/21/98	1307	AIDS	042.
5/21/98	1315	AIDS	042.
5/21/98	1317	General Anxiety Disorder	304.0
5/21/98	1319	HIV	042.
5/21/98	1324	Rotator Cuff Syndrome	
5/21/98	1341	Disabling HIV	042.
5/21/98	1352	Cervical Cancer	233.1
5/21/98	1359	Nausia	787.02
5/21/98	1392	PGW Syndrome, Fibromalgia	729.1
5/21/98	1392	PGW Syndrome, Fibromalgia	729.1
5/21/98	1421	Dysthimic Disorder	300.4
5/21/98	1422	AIDS	042.
5/21/98	1423	Chronic Pain from Degenerative Joint	
5/21/98	1429	AIDS	042.
5/21/98	1433	AIDS	042.
5/21/98	1433	AIDS	042.
5/21/98	1444	AIDS	042.
5/21/98	1444	AIDS	042.
5/21/98	1452	AIDS	042.
5/21/98	1455	Chronic Pain	
5/21/98	1472	AIDS	042.
5/21/98	1474	AIDS	042.
5/21/98	1493	AIDS	042.
5/21/98	1498	AIDS	042.

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	1512	Nuerological [*sic*] Anoymoly	345.9
5/21/98	1517	Post Traumatic Arthritis	716.
5/21/98	1519	AIDS	042.
5/21/98	1522	HIV	042.
5/21/98	1534	Stress/Depression	300.4
5/21/98	1538	AIDS	042.
5/21/98	1541	HIV	042.
5/21/98	1567	HIV	042.
5/21/98	1598	Chronic Pain –Arthritis – Depression	716
5/21/98	1599	Generalized Anxiety Disorder	300.0
5/21/98	1602	Arthiritis	716
5/21/98	1607	Chronic Pain	724.0
5/21/98	1612	HIV Disabling	042.
5/21/98	1613	Arthiritis	716.94
5/21/98	1620	Arthritic—Lim Pain	721.90
5/21/98	1621	H.I.V.	042.
5/21/98	1628	AIDS	042.
5/21/98	1633	AIDS	042.0
5/21/98	1635	H.I.V.	042.0
5/21/98	1657	H.I.V.	042.
5/21/98	1658	Dysthmia	
5/21/98	1660	Arthiritis	716.5
5/21/98	1662	H.I.V.	042.
5/21/98	1663	AIDS	042.
5/21/98	1663	AIDS	042.
5/21/98	1665	Pain and Headaches	
5/21/98	1670	Back Pain, T-Spine	724.1
5/21/98	1675	Scholiosis	754.2

Date	Member#	Specific Diagnosis	ICD-9-CM
5/21/98	1676	AML Leukemia	204.0
5/21/98	1701	AIDS	042.
5/21/98	1705	Endometriosis, Chronic Pelvic Pain	

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-0088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OF MICHAEL M. ALCALAY, M.D., M.P.H. IN SUPPORT OF MOTION TO DISSOLVE OR MODIFY PRELIMINARY INJUNCTION ORDER

I, MICHAEL M. ALCALAY, M.D., declare:

1. I am Medical Director of the Oakland Cannabis Buyers' Cooperative (the "Cooperative" or "OCBC"). As Medical Director I am familiar with the policies and procedures of the OCBC. I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. I am a Board-certified pediatrician. I graduated from U.C.L.A. medical school in 1968. I received a Masters Degree in public health in 1973 from the University of California Berkeley School of Public Health. I practiced as a pediatrician in the Northern California Kaiser Hospitals until 1995 when I became ill with an AIDS related illness.

3. As Medical Director of the Cooperative I attend regular board meetings and consortium meetings. Other duties include acting as liaison between the Cooperative and patient-members' authorizing physicians and doing patient outreach. As a result of my duties as Medical Director, I am knowledgeable about many Cooperative patients and their medical conditions.

4. Since October 20, 1998, the OCBC has not engaged in the manufacture or distribution of cannabis from its premises, or used the premises for the purpose of manufacturing or distributing cannabis. The OCBC has remained open for limited purposes including: conducting support groups for patients suffering from a variety of medical conditions; providing massage therapy for patient-members; conducting member intake procedures and verifying physician recommendations and approvals; issuing identification cards on behalf of the City of Oakland pursuant to Oakland municipal law; conducting meetings regarding medical cannabis research; providing meals for patient-members; furnishing a meeting space for various community groups; selling books and T-shirts; responding to telephone inquiries regarding medical cannabis issues; and administrative activities.

5. As Medical Director, I have reviewed and am generally familiar with the medical circumstances that have led patient-members to seek medical cannabis. I have witnessed the devasting effect of the OCBC's inability to provide cannabis to these members.

6. I am personally aware that patient-members of the Cooperative suffer from debilitating and often

deadly diseases, including HIV and/or AIDS, cancer, arthritis, multiple sclerosis, and glaucoma—to name a few. I have seen and am aware that medical cannabis provides relief to patient-members as a pain reliever, an appetite stimulant, an anti-nauseant, and as relief from spasticity. Medical cannabis relieves intraocular eye pressure in patient-members who suffer from glaucoma. Patient-members who have not been able to receive cannabis have been unable to eat, have suffered excruciating pain and debilitating side effects. Some have died.

7. I am also a patient-member of the Cooperative. I learned I was HIV-positive in 1986. I was first diagnosed with AIDS in 1993. In 1995, I became very seriously ill with an AIDS-related condition caused by a microbe called cryptosporidium that caused me to have constant diarrhea. I experienced a dramatic loss of my appetite, and I also suffered generally from apathy. I was suffering from the classic "wasting syndrome" that is associated with many AIDS patients. When I eventually medicated myself with cannabis, I regained my appetite, and I was finally able to regain weight again. The cannabis kept me alive until a therapy could be found to eradicate the microbe from my body.

8. I have been required to take a lot of different medications to treat my AIDS condition, including the drug AZT and a variety of different protease inhibitors. I need these medications in order to live. But these medicines cause nausea and vomiting. To combat the nausea I have tried several prescription drugs including Marinol and Atarax, but none of them have worked for me. Cannabis has been the only medicine that has

worked for me to control the nausea and vomiting caused by my AIDS medications.

9. I am aware that patient-members (including myself) suffer from serious medical conditions such as AIDS-related "wasting snydrome" and those with cancer undergoing chemotherapy experience nausea and severe appetite deficits. Patients, such as myself, also suffer these same conditions as a result of having to take multiple medications to treat AIDS, some of them new or experimental. I am aware that medical cannabis relieves these symptoms in patients and enables them to eat. Medical cannabis prolongs some of these patients' lives (including my own). Without the necessary cannabis, patients are unable to take the other medications (in the case of AIDS patients) or to continue to undergo the intensive chemotherapy (in the case of cancer patients) in order to stay alive. If the patients do not have access to cannabis these patients will suffer imminent harm. Cannabis is necessary for the treatment of these patients' medical conditions. For some of these patients cannabis will alleviate the medical condition or symptoms associated with it. For these patients, there is no legal alternative to cannabis for the effective treatment of the patients' medical condition because the patients have tried legal alternatives to cannabis and have found them ineffective in treating his or her condition, or have found that such alternatives result in intolerable side effects. Thus, these patients have no reasonable alternative to medical cannabis. I believe, based on personal experience, that supplying medical cannabis to these patient-members is necessary to avert imminent and often life-threatening harm.

10. I am aware that the patient-members suffer from serious medical conditions such as multiple sclerosis or quadriplegia. These patient-members experience debilitating spasticity and/or constant pain. If these patients do not have access to cannabis these patients will suffer imminent harm such that they are forced to live with uncontrollable muscular spasticity and to endure debilitating pain throughout every day. Cannabis is necessary for the treatment of these patients' medical condition. For some of these patients, cannabis will alleviate the medical condition or symptoms associated with the multiple sclerosis or quadriplegia. For these patients, there is no legal alternative to cannabis for the effective treatment of the patients' medical condition because the patients have tried legal alternatives to cannabis and have found them ineffective in treating his or her condition, or has found that such alternatives result in intolerable side effects. Thus, these patient-members have no reasonable alternative to medical cannabis. I believe that supplying medical cannabis to these patient-members is necessary to avert imminent and often-life threatening harm.

11. Patient-members have been forced to endure further harm by the OCBC's inability to provide medical cannabis. Several of the patient-members are now deceased. They died from illnesses including cancer, AIDS, and cachexia. Patient-members John Odell, Elizabeth Schoen, Willie Beal, Paul Allen, Miles Sanders and Walter Hatchett have died. Access to medical cannabis may have offered them a chance at recovery, minimized their suffering, or even prolonged their life.

12. Many patient-members' lives have been jeopardized since the preliminary injunction was issued. Patient-members have been forced to try to obtain cannabis from alternative and unsafe sources. They are placed in danger both because the act of purchasing from unauthorized sources such as street dealers is inherently dangerous and because impurities in marijuana purchased on the street may be harmful to their fragile health. Some patient-members have chosen to forego their medication altogether because of the severe and harmful risks associated with these alternative sources. These patients have faced months of needless pain and worsening of the severe symptoms associated with their illnesses. Some of these patients even face death because they do not have safe lawful access to medical cannabis.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 29th day of May, 2000, at Oakland, California.

/s/ MICHAEL M. ALCALAY, M.D., M.P.H.
MICHAEL M. ALCALAY, M.D., M.P.H.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

No. C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE,
AND JEFFREY JONES, DEFENDANTS

[Filed Jan 9, 1998]

DECLARATION OF SPECIAL AGENT
BRIAN NEHRING

I, BRIAN NEHRING, do hereby declare and say as follows:

1. I am a Special Agent with the San Francisco Field Division of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since September 1991.

2. I have received training from the DEA and Federal Bureau of Investigation in specialized narcotic investigative matters including, but not limited to, the following: drug interdiction and detection, money laundering techniques and schemes, drug identification, and asset identification and forfeiture. This training included specialized training in the preparation of nar-

cotic and document search warrants for residences and businesses.

3. I have participated in numerous investigations specifically involving both the indoor and outdoor manufacture or cultivation of marijuana. In the course of these investigations, I have personally participated in the eradication of over 1,000 indoor and 10 outdoor marijuana plants, and the arrest of more than 100 individuals for violations of federal and state law regarding controlled substances. I also have received specialized training regarding the techniques used to grow marijuana. Based on my experience and training, I am familiar with the smell and appearance of growing and processed marijuana, as well as the smell of marijuana when it is burning. I also have participated in the obtaining and/or execution of over 100 federal and California state warrants to search a particular place or premises for controlled substances and/or related paraphernalia, indicia, and other evidence of the commission of state and/or federal felony violations of law.

4. On May 19, 1997, I made an undercover purchase of one-eighth ounce of marijuana with the brand name of "Northern Lights" for $40 from the Oakland Cannabis Buyer's Cooperative ("OCBC"), a marijuana distribution business located at 1755 Broadway Avenue, in Oakland, California. I made this undercover purchase using an undercover name, identification, and a phony physician statement. The circumstances of this undercover purchase are as follows:

5. On May 19, 1997, I was provided with Official Authorized Funds and a phony physician statement, in anticipation of making an undercover purchase of mari-

juana from the OCBC. The phony physician statement used my undercover identity as the patient's name, and stated that this person suffered from "Post-Traumatic Stress Disorder." The marijuana distribution center designated was the "Oakland CBC." The doctor listed on the statement also was a phony identity. A telephone number for the doctor listed on the statement was for an undercover telephone line to the DEA San Francisco.

6. At approximately 1:55 p.m., I approached the entrance of the OCBC and entered into a small lobby area which led to an elevator and staircase, where a unidentified adult male dressed as a uniformed security guard was seated behind a desk. The guard informed me that he would have to see my identification and physician statement, which I produced. The guard then directed me to the third floor of the building and told me to take the staircase, being that the elevator did not work. I walked up the staircase to the third floor of 1755 Broadway Avenue, along with three other apparent OCBC customers.

7. Upon reaching the third floor, I was met by an unidentified adult male ("UM1") who gave me a form to fill out and took my physician statement to another room at the rear of the floor. The form I was handed, when blank, asked for the customer's name, address, phone number, physician's name, illness, what illnesses or conditions the customer had suffered from, what medications the customer was taking, whether the customer had ever used marijuana before, and how the customer had used marijuana before (smoked, eaten, etc.). I completed the form using my undercover

identity, and listed "Post Traumatic Stress Disorder" as my ailment.

8. While completing this form, I observed two small children, approximately 2-4 years of age, in the company of an adult who appeared to be working for the OCBC.

9. UM1 then led me down a hallway to a room where I was interviewed by another adult male who introduced himself as "Jim." "Jim" told me that, although the OCBC had not been able to contact "Dr. Eastwood," my forms appeared acceptable. "Jim" then gave me an OCBC membership card. The front of the card contains the OCBC symbol on the left, the OCBC's name on the right, and blank listings for the customer's membership number and name. The customer's name was filled in with my undercover identity. The back of the card lists the OCBC's hours as 11:00 a.m. to 7:00 p.m. on Monday and Friday, and 11:00 a.m. to 1:00 p.m., and 5:00 p.m. to 7:00 p.m., from Tuesday through Thursday, and contains blank listings for the customer's name, address, and phone number. My undercover identity was again listed on the back of the card, along with an undercover address and telephone number. The membership card did not contain picture identification.

10. "Jim" then led me down a hallway to a room which "Jim" referred to as the "bar room." In this room, I observed two individuals standing behind a large glass display case containing numerous samples of marijuana. I also observed an adult male smoking marijuana while sitting in a chair on the opposite side of the room. The smell of burning marijuana was readily

apparent. This individual was sitting next to a display case which contained two large growing marijuana plants under lights, and I also observed several large marijuana plants growing in a Mylar-lined display case at the opposite corner of the room.

11. "Jim" informed me that I would be able to purchase one-quarter ounce of marijuana per visit, and then introduced me to an unidentified adult male ("UM2") who was in charge of distributing the marijuana. UM2 informed me that the OCBC currently had seven kinds of marijuana for sale, all displayed, which he claimed ranged in price from between $28 to $85 per one-eighth ounce. UM2 also said that the OCBC was sold out of the Mexican-grown marijuana, which ordinarily sold for $28 per one-eighth ounce.

12. I then purchased one-eighth ounce of what the OCBC identified as marijuana with the "brand name" of "Northern Lights" for $40.

13. At approximately 2:25 p.m., I exited the OCBC, and subsequently met with two fellow Special Agents at a designated rendezvous location, whereupon I turned over the bag of suspected marijuana to these agents for evidentiary purposes.

14. The bag of suspected marijuana which I purchased from the OCBC on May 19, 1997, was subsequently marked as Exhibit 11, and transferred to the DEA Western Regional Laboratory for analysis.

15. During this visit to the OCBC to establish membership, I did not observe any other commercial

activity ongoing at the OCBC except for the distribution of marijuana.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ BRIAN NEHRING
BRIAN NEHRING

Executed this 5th day of January 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

No. C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE,
AND JEFFREY JONES, DEFENDANTS

[Filed Jan 9, 1998]

DECLARATION OF SPECIAL AGENT BILL NYFELER

I, BILL NYFELER, do hereby declare and say as follows:

1. I am a Special Agent with the San Francisco Field Division of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since October 1995.

2. I have received training from the DEA, Federal Bureau of Investigation, and the California Narcotics Officers Association, in specialized narcotic investigative matters including, but not limited to, the following: drug interdiction and detection, money laundering techniques and schemes, drug identification, and asset identification and forfeiture. This training included specialized training in the preparation of narcotic and

document search warrants for residences and businesses.

3. I have participated in numerous investigations specifically involving both the indoor and outdoor manufacture or cultivation of marijuana. In the course of these investigations, I have personally participated in the eradication of over 500 indoor and 5,000 outdoor marijuana plants, and the arrest of more than 50 individuals for violations of federal and state law regarding controlled substances. I also have received specialized training regarding the techniques used to grow marijuana. Based on my experience and training, I am familiar with the smell and appearance of growing and processed marijuana, as well as the smell of marijuana when it is burning. I also have participated in the obtaining and/or execution of over 50 federal and California state warrants to search a particular place or premise for controlled substances and/or related paraphernalia, indicia, and other evidence of the commission of state and/or federal felony violations of law.

4. On June 23, 1997, I made an undercover purchase of one-eighth ounce of Mexican-grown marijuana for $7 from the Oakland Cannabis Buyers' Cooperative ("OCBC"), a marijuana distribution business located in a building at 1755 Broadway Avenue, in Oakland, California. I made this undercover purchase using the OCBC membership card that had been previously issued to Special Agent Brian Nehring. The circumstances of this purchase are as follows:

5. On June 23, 1997, I was provided with Official Authorized Funds and equipped with audio and video equipment in anticipation of making an undercover

purchase of marijuana from the OCBC. I also was provided with the OCBC membership card which had previously been issued to Special Agent Nehring.

6. At approximately 2:55 p.m., I approached the entrance of 1755 Broadway Avenue, entered into a small lobby area, and flashed the OCBC membership card previously issued to Special Agent Nehring to an unidentified adult male dressed in a security guard uniform. The guard allowed me to enter, and did not ask me to provide any further identification.

7. Upon entering the elevator, I observed a sign stating that the OCBC had moved to the third floor of the building, and rode the elevator to the third floor. Upon arriving at the third floor, I walked to a desk where an unidentified adult male ("UM1") asked me to produce my membership card. I showed UM1 the OCBC membership card previously issued to Special Agent Nehring, and was allowed to enter the OCBC. I was not asked to provide any other form of identification.

8. I then proceeded to walk through the OCBC. While doing so, I observed approximately fifty marijuana plants in various stages of growth, from small clones to large flowering adult plants. Some of the plants were labeled "Educational Grow." I also observed three customers standing in line at the sales counter purchasing marijuana. Two other customers were looking at the marijuana plants, and then walked to the sales counter to purchase marijuana.

9. I then approached a sales counter, which contained several plastic bags containing green leafy

material at different prices. An unidentified adult male ("UM2") behind the counter asked me if he could help me. I responded that I wished to purchase one-eighth ounce of Mexican-grown marijuana.

10. UM2 then handed me a clear plastic bag containing a green, leafy substance, and I handed him $7 in return.

11. At approximately 3:00 p.m., I exited the OCBC, and subsequently met with a fellow Special Agent at a designated rendezvous location, whereupon I turned over the bag of suspected marijuana to this agent for evidentiary purposes.

12. The bag of suspected marijuana which I purchased from the OCBC on June 23, 1997, was subsequently marked as Exhibit 11, and transferred to the DEA Western Regional Laboratory for analysis.

13. In addition, the audio and video equipment which I utilized during my undercover purchase of marijuana from the OCBC on June 23, 1997, successfully recorded this purchase. The original tapes and recordings are currently maintained by a non-drug evidence custodian of the San Francisco Field Division of the DEA.

14. During this visit to the OCBC to make an undercover purchase of marijuana, I did not observe any other commercial activity ongoing at the OCBC except for the distribution of marijuana.

15. On September 10, 1997, I made an undercover purchase of one-eighth ounce of "AA" Mexican-grown

marijuana for $15 from the OCBC, using the OCBC membership card that had been previously been issued to Special Agent Nehring. The circumstances of this purchase are as follows:

16. On September 10, 1997, I was provided with Official Authorized Funds and the OCBC membership card previously issued to S/A Nehring, in anticipation of making an undercover purchase of marijuana from the OCBC.

17. At approximately 11:10 a.m., I approached the building at 1755 Broadway Avenue and entered into a small lobby area, where an unidentified adult male who was dressed as a security guard and seated behind a desk was playing what appeared to be a "Game Boy" handheld device. Although I had taken the OCBC membership card previously issued to Special Agent Nehring out of my pocket, I passed the security guard without showing him this card or any identification, and walked to the elevator, where a second unidentified adult male ("UM1") was also waiting for the elevator. UM1 stated that he also was going to the OCBC and, upon noticing the membership card in my hand, mentioned that I could get a new, plastic membership card with my picture on it for only $10. I thanked UM1 for the information. At this time, the security guard put down his "Game Boy," and asked me to show him my membership card. I flashed the OCBC membership card previously issued to Special Agent Nehring, and was allowed to enter the elevator.

18. Upon arriving at the third floor, I approached the front desk, showed the OCBC membership card previously issued to Special Agent Nehring, and in-

quired about obtaining a new membership card. An unidentified adult male ("UM2") seated behind the desk told me that I would have to fill out an information card. The form, when blank, asked for the customer's name, address, phone number, physician's name, illness, whether the customer had ever used marijuana before, and how the customer had used marijuana before (smoked, eaten, etc.). I completed the form using Special Agent Nehring's undercover identity. UM2 then took two pictures of me, and informed me that my new membership card would be ready in approximately 30 days. UM2 also gave me a temporary membership card, and informed me that I could use the temporary card until I had received the new membership card.

19. UM2 then asked me if I had been to the OCBC since it had moved from the fifth floor to the third floor. I responded that I had not, and UM2 gave me a brief tour of the OCBC. When we reached the marijuana sales area, which UM2 called the "Budbar," UM2 informed me that smoking and rolling marijuana cigarettes was only allowed in the "Budbar," and that when anyone left the "Budbar," all marijuana must be kept hidden in a pocket or paper bag. During this tour, I observed approximately 10 growing marijuana plants in the hallway, under a sign which read "Educational Grow."

20. I then approached the sales counter, where there were approximately 8-10 other customers standing in line waiting to purchase marijuana. While waiting, I observed a sign on the sales counter stating that the OCBC accepted Visa, Mastercard, and ATM cards. When I reached the front of the line, I asked an unidentified adult female ("UF1") behind the sales counter

for one-eighth ounce of "AA" Mexican-grown marijuana. UF1 handed me several bags containing a green, leafy substance, and informed me that, "it's really good, I've just smoked some myself."

21. I then chose one of the bags, and handed $15 to UF1.

22. At approximately 11:25 a.m., I exited the OCBC, and subsequently met with two fellow Special Agents at a designated rendezvous location, whereupon I turned over the bag of suspected marijuana to these agents for evidentiary purposes.

23. The bag of suspected marijuana which I purchased from the OCBC on September 10, 1997, was subsequently marked as Exhibit 37, and transferred to the DEA Western Regional Laboratory for analysis.

24. During this visit to the OCBC to make an undercover purchase of marijuana, I did not observe any other commercial activity ongoing at the OCBC except for the distribution of marijuana.

25. On November 14, 1997, I made an undercover purchase of one-eighth ounce of marijuana with the brand name of "House Special" for $45 from the OCBC, using the temporary OCBC membership card issued to me on September 10, 1997 in the name of Special Agent Nehring's undercover identity. The circumstances of this purchase are as follows:

26. On November 14, 1997, I was provided with Official Authorized Funds and the OCBC temporary membership card previously issued to me on Septem-

ber 10, 1997 in the name of Special Agent Nehring's undercover identity, in anticipation of making an undercover purchase of marijuana from the OCBC. I had obtained this temporary membership card from the OCBC during my previous visit to the club on September 10, 1997. On that date, I had entered the OCBC using the membership card previously originally issued to Special Agent Nehring on May 19, 1997. I never was asked to prove that I was the person named on this membership card during this visit, and was issued the temporary membership card in the name of Special Agent Nehring's undercover identity, until a permanent card with my picture was ready.

27. At approximately 2:55 p.m., I entered the front door of the building located at 1755 Broadway Avenue, and showed the OCBC temporary membership card to an unidentified adult male dressed as a security guard, and proceeded to take the elevator to the third floor. Upon arriving at the third floor, I approached the desk and produced the temporary OCBC membership card, explaining that I was there to pick up my picture membership card. The clerk informed me that the picture membership card was ready, and that the cost was $10.

28. I handed the clerk $10 in Official Authorized Funds, and the clerk handed me a white plastic identification card. The front of the card contains the OCBC logo and symbol on the left side, under which is the name of Special Agent Nehring's undercover identity, and the phony address, phone number, and other identifying information of this individual. The "issue date" was listed as 9/30/97. The right side of the card contained a picture of myself, and my signature in the name of Special Agent Nehring's undercover identity.

The back of the card contained a "Certificate of Membership" and OCBC description, with a bar code strip, and listed Jeffrey W. Jones and Matthew J. Quirk as the Co-Founders of the OCBC.

29. After I received the picture membership card, I proceeded to the "Budbar" area of the OCBC, and showed the new membership card to the guard sitting near the door. I then approached the sales counter, and observed several clear plastic baggies which contained a green, leafy material. The sales counter also contained several small bottles marked "Small Hash Oil—$30," and "Large Hash Oil—$60." I also observed a small black square substance that was labeled "Afghani Hash, 20 grams—$400." I further observed that the hydroponic marijuana grow display still contained several live marijuana plants.

30. An unidentified adult male ("UM1") approached me from behind the sales counter and asked me how he could help me. I asked for one-eighth ounce of the "House Special." UM1 stated that this would cost $45. I handed UM1 $45, and UM1 gave S/A Nyfeler a clear plastic baggie containing approximately one-eighth ounce of a green, leafy substance. I thanked UM1 and departed the "Budbar."

31. At approximately 3:05 p.m., I exited the OCBC, and subsequently met with a fellow Special Agent at a designated rendezvous location, whereupon I turned over the bag of suspected marijuana to these agents for evidentiary purposes.

32. The bag of suspected marijuana which I purchased from the OCBC on November 14, 1997, was

subsequently marked as Exhibit 55, and transferred to the DEA Western Regional Laboratory for analysis.

33. During this visit to the OCBC to make an undercover purchase of marijuana, I did not observe any other commercial activity ongoing at the OCBC except for the distribution of marijuana.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ BILL NYFELER
BILL NYFELER

Executed this 8th day of January 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

No. C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE,
AND JEFFREY JONES, DEFENDANTS

[Filed Jan 9, 1998]

DECLARATION OF SPECIAL AGENT CAROLYN PORRAS

I, CAROLYN PORRAS, do hereby declare and say as follows:

1. I am a Special Agent with the San Francisco Field Division of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since August 1996.

2. I have received training from the DEA and Federal Bureau of Investigation in specialized narcotic investigative matters including, but not limited to, the following: drug interdiction and detection, money laundering techniques and schemes, drug identification, and asset identification and forfeiture. This training included specialized training in the preparation of nar-

cotic and document search warrants for residences and businesses.

3. I have participated in numerous investigations specifically involving both the indoor and outdoor manufacture or cultivation of marijuana. In the course of these investigations, I have personally examined approximately 15 indoor and outdoor marijuana plants. I also have participated in the arrest of more than 30 individuals for violations of federal and state law regarding controlled substances. I also have received specialized training regarding the techniques used to grow marijuana. Based on my experience and training, I am familiar with the smell and appearance of growing and processed marijuana, as well as the smell of marijuana when it is burning. I also have participated in the obtaining and/or execution of five federal and California state warrants to search a particular place or premises for controlled substances and/or related paraphernalia, indicia, and other evidence of the commission of state and/or federal felony violations of law.

4. On August 8, 1997, I made an undercover purchase of one-eighth ounce of marijuana for $25 from the Oakland Cannabis Buyers' Cooperative ("OCBC"), a marijuana distribution business located in a building at 1755 Broadway Avenue, in Oakland, California. I made this undercover purchase using the OCBC membership card that had been previously been issued to Special Agent Brian Nehring. The circumstances of this purchase are as follows:

5. On August 8, 1997, I was provided with Official Authorized Funds and the OCBC membership card previously issued to Special Agent Nehring, in antici-

pation of making an undercover purchase of marijuana from OCBC.

6. At approximately 2:57 p.m., I approached the building at 1755 Broadway Avenue, and walked into the building and entered into a lobby area, where an unidentified adult male dressed as a security guard inquired where I was going. In response, I flashed the membership card previously issued to Special Agent Nehring, and continued to walk toward the elevator. As I hit the elevator button, I noticed a sign advising that the OCBC had moved from the fifth floor to the third floor.

7. Upon arriving at the third floor, I approached a room containing a desk, file cabinets, sofas, and a door leading to entrances to other rooms. I then was approached by an unidentified adult female ("UF1"), who asked me if I was there to make a purchase. I responded that I was. UF1 then asked me for my memberhip card, and I gave her the OCBC membership card previously issued to Special Agent Nehring. UF1 then yelled out the membership number to an unidentified adult male ("UM1") seated in the same room. A few seconds later, UM1 informed UF1 that the membership number which she had called out was closed.

8. I asked UF1 why the membership number was closed. UF1 stated that a possibility could be that the file doesn't have a physician letter but that she (UF1) would check. I then observed UF1 hand over the membership card to a second unidentified adult male ("UM2"), who walked over to a room where there were at least two computers inside. A few seconds later, UM2, after appearing to work on one computer for a

moment, returned and instructed UF1 to reopen the file.

9. UF1 then asked S/A Porras whether the person named on the membership card (Special Agent Nehring's undercover identity) had called to notify the OCBC that a third party would be making a purchase for him. I responded that I thought that this person had called, but that this person was very sick, and thus I could not be sure whether he in fact had called. UF1 explained to me that, as an alternative, I needed to have a letter from this person authorizing me to make purchases for him. I responded that I would do that the next time, but asked to be allowed to make a purchase on that day. UF1 stated that I would be allowed to make a purchase for that day only.

10. I then was instructed to go out into another room at the end of the hallway. When I asked for directions, I was told to "follow my nose." I proceeded to walk down and enter a large room at the end of the hallway, where the smell of burning marijuana was readily apparent. In this room, I observed at least fifteen marijuana plants being grown, with lights, fans, and timer clocks pointed directly at the plants.

11. I then proceeded to walk towards the glass sales counter which contained several clear plastic baggies containing green, leafy material. Approximately 4-5 other customers were standing in line in front of me. When I reached the front of the line, a second unidentified adult female ("UF2") asked me what I wanted to purchase. I pointed to a clear plastic baggie labeled "Mexican AA-Grade A," for $25 for one-eighth ounce.

12. I then purchased one-eighth ounce of the OCBC identified as Mexican-grown marijuana for $25.

13. As I turned to leave the OCBC, I observed approximately 5-10 individuals standing in line behind me, apparently to purchase marijuana from the OCBC.

14. At approximately 3:10 p.m., I exited the OCBC, and subsequently met with two fellow Special Agents at a designated rendezvous location, whereupon I turned over the bag of suspected marijuana to these agents for evidentiary purposes.

15. The bag of suspected marijuana which I purchased from the OCBC on August 5, 1997, was subsequently marked as Exhibit 33, and was transferred to the DEA Western Regional Laboratory for analysis.

16. During this visit to the OCBC to make an undercover purchase of marijuana, I did not observe any other commercial activity ongoing at the OCBC except for the distribution of marijuana.

17. On October 22, 1997, I received a message on the DEA undercover line from a "Nurse Laura Lee," who wanted to confirm that the "doctor" had signed the physician statement used by Special Agent Deborah Muusers, acting in an undercover capacity, to make an undercover purchase of marijuana from the OCBC. Thereafter, at approximately 3:40 p.m., acting in an undercover capacity, I answered a call made to the same undercover telephone line. An individual who identified himself as "Shawn," and who claimed to be calling from the OCBC, inquired whether the address listed on the phony physician statement used by Special

Agent Muusers had a suite number or floor, or whether the address was a house. I told "Shawn" that the address was the first floor. "Shawn" then stated that the OCBC wanted to send a representative to the office to meet with the doctor. I responded that I was walking out the door. "Shawn" inquired what time the doctor would be in the following day, to which I responded that the doctor would be in after 10:00 a.m.

19. Later on October 22, 1997, at approximately 4:25 p.m., acting in an undercover capacity, I called "Shawn" at 510-832-5346, and informed him that I was a new doctor to the Bay Area and didn't want involvement with the OCBC if persons from the club were planning on visiting me. I further informed "Shawn" that I was requesting that the OCBC cancel this patient's membership. "Shawn" responded, "We already did."

I declare under penalty of perjury that the foregoing is true and correct.

/s/ CAROLYN PORRAS
CAROLYN PORRAS

Executed this 8th day of January 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

No. C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE,
AND JEFFREY JONES, DEFENDANTS

[Filed Jan 9, 1998]

DECLARATION OF SPECIAL AGENT
DEBORAH MUUSERS

I, DEBORAH MUUSERS, do hereby declare and say as follows:

1. I am a Special Agent with the San Francisco Field Division of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since July 1991.

2. I have received training from the DEA in specialized narcotic investigative matters including, but not limited to, the following: drug interdiction and detection, money laundering techniques and schemes, drug identification, and asset identification and forfeiture. This training included specialized training in the

preparation of narcotic and document search warrants for residences and businesses.

3. I have participated in numerous investigations specifically involving both the indoor and outdoor manufacture or cultivation of marijuana. In the course of these investigations, I have personally examined approximately 250 indoor and outdoor marijuana plants. I also have participated in the arrest of more than 100 individuals for violations of federal and state law regarding controlled substances. I also have received specialized training regarding the techniques used to grow marijuana. Based on my experience and training, I am familiar with the smell and appearance of growing and processed marijuana, as well as the smell of marijuana when it is burning. I also have participated in the obtaining and/or execution of more than 100 federal and California state warrants to search a particular place or premises for controlled substances and/or related paraphernalia, indicia, and other evidence of the commission of state and/or federal violations of law.

4. On October 22, 1997, I made an undercover purchase of one-eighth ounce of marijuana with the brand name of "That's Purdy" for $60 from the Oakland Cannabis Buyers' Cooperative ("OCBC"), a marijuana distribution business located at 1755 Broadway Avenue, in Oakland, California. I made this undercover purchase using an undercover name, identification, and a phony physician statement. The circumstances of this purchase are as follows:

5. On October 24, 1997, I was provided with Official Authorized Funds and a phony physician statement, in anticipation of making an undercover purchase of mari-

juana from the Marin Alliance. The phony physician statement used by my undercover identity as the patient's name, and stated that this person suffered from "Menstrual Cramps." The marijuana distribution center designated was the "Oakland C.B.C." The doctor listed on the statement also was a phony identity. A telephone number for the doctor listed on the statement was for an undercover telephone line to the DEA San Francisco. I also was provided with a concealed video and audio recording device with microphone.

6. At approximately 11:05 a.m., I entered the building at 1755 Broadway Avenue, and was stopped by an unidentified adult male wearing a security guard's uniform, who asked me what was my business. I told the guard that I wanted to establish membership, to which the guard responded that I needed a piece of paper from a doctor. I informed the guard that I had a document from a doctor, whereupon the guard asked to see the document and my driver's license. I produced the phony physician statement and my undercover identification, and was directed up the stairs to a reception area, as the elevator was inoperable. As I passed him, the guard announced on a hand-held radio that I was on my way up to "intake."

7. I walked upstairs and along a corridor into a reception area, where I came upon an adult male sitting behind a desk, upon which there was a nameplate with the name "Shawn." I informed "Shawn" that I wished to establish membership at the OCBC, and produced the phony physician statement and my undercover identification. "Shawn" gave me several forms to fill out, including a registration form asking for a bio-

graphical data, such as the ailment for which the customer wished to purchase marijuana, and a medical release form that would allow the OCBC to call a patient's doctor to divulge patient information. I filled out these forms, and listed "menstrual cramps" as my medical ailment. "Shawn" photocopied my phony physician statement and undercover identification, and returned both originals to me.

8. "Shawn" then gave me a temporary membership card. The front of the card contains the OCBC symbol on the left, the OCBC's name on the right, and blank listings for the customer's membership number and name. The customer's name was filled in with my undercover identity. At the top of the card, the words, "Exp. 11/22/97 *Need photo taken," were written in. The back of the card lists the OCBC's hours as 11:00 a.m. to 7:00 p.m. on Monday and Friday, and 11:00 a.m. to 1:00 p.m., and 5:00 p.m. to 7:00 p.m., from Tuesday through Thursday, and contains blank listings for the customer's name, address, and phone number. None of these listings were filled in. The membership card did not contain picture identification.

9. "Shawn" then informed me that, during the next visit to the OCBC, a photo would be taken in-house, after the club's camera had been set up, and a undetermined fee would be charged. "Shawn" then directed me to the "bar," which was back along the corridor. During this period, I observed three other individuals enter the reception area to speak with "Shawn."

10. I then walked down the corridor and came upon a second adult male dressed in a guard's uniform, stationed at a desk at the entrance to the "bar." I showed

the guard my temporary membership card and was allowed into the "bar." The "bar" area consisted of a large room with several couches in a sitting area, and several glass counters with various items enclosed within. Inside one of the glass cases were approximately 20-25 6"-8" inch marijuana plants growing inside. Against one wall of the "bar" area was a cubicle with grow lights and approximately 5-6 larger plants, approximately 3'-3 1/2' tall. One glass counter contained various food items that purported to contain marijuana, including brownies and rice krispie treats. Another glass counter contained drug paraphernalia, including pipes. A third glass counter contained samples of what was purported to be marijuana, ranging in quantity from 1 gram to one-eighth ounce. For the one-eighth ounce quantity, the prices ranged from $15 to $60. I observed approximately 3-4 individuals sitting on the couches, and there were approximately 5-6 other customers waiting in line to purchase marijuana. The smell of burning marijuana was readily apparent.

11. When I reached the front of the line, I spoke to an unidentified adult male ("UM1") behind the counter, and asked to purchase one-eighth ounce of marijuana with the "brand name" of "That's Purdy." UM1 proceeded to take two ziploc baggies, each containing what appeared to be marijuana, from a container, and placed the baggies on the counter. I chose one of the baggies, and gave UM1 $60 in return. UM1 placed the $60 in a cash register.

12. At approximately 11:30 a.m., I exited the OCBC, and subsequently met with two fellow Special Agents at a designated rendezvous location, whereupon I

turned over the bag of suspected marijuana to these agents for evidentiary purposes.

13. The bag of suspected marijuana which I purchased from the OCBC on October 22, 1997, was subsequently marked as Exhibit 41, and was transferred to the DEA Western Regional Laboratory for analysis.

15. In addition, the audio and video equipment which I utilized during my undercover purchase of marijuana from the OCBC on October 22, 1997, successfully recorded this purchase. The original tapes and recordings are currently maintained by a non-drug evidence custodian of the San Francisco Field Division of the DEA.

16. During this visit to the OCBC to establish membership, I did not observe any other commercial activity ongoing at the OCBC except for the distribution of marijuana.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ DEBORAH MUUSERS
DEBORAH MUUSERS

Executed this 8th day of January 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, AND
JEFFREY JONES, DEFENDANTS

[Filed: Jan. 9, 1998]

DECLARATION OF PHYLLIS E. QUINN

I, PHYLLIS E. QUINN, do hereby declare and say as follows:

1. I am a Senior Forensic Chemist with the Western Laboratory of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since November 1983.

2. My principal duty with the DEA Western Laboratory is the analysis of controlled substances. Prior to my current position, I served as a Forensic Chemist with the NIS Regional Laboratory in Pearl Harbor, Hawaii, from September 1981 to November 1983, and as a Forensic Chemist with the Bureau of

Forensic Sciences in Richmond, Virginia, from October 1978 to August 1981. My principal duty in both positions was the analysis of controlled substances.

3. I received a Bachelor of Science in Chemistry from Mary Washington College, in Fredericksburg, Virginia, in 1977, and a Master of Science in Forensic Chemistry from the University of Pittsburgh, in Pittsburgh, Pennsylvania, in 1978. Since 1979, I have taken numerous additional courses and seminars on various issues involving forensic chemistry, including several specifically related to the analysis of controlled substances. Among others, these courses and seminars were sponsored by the DEA; American Chemical Society; McCrone Institute; Bowdoin College; and United States Environmental Protection Agency. I also have published articles related to the analysis of methamphetamine and phencyclidine ("PCP") in *Microgram* and the *Journal of Analytical Toxicology*. I am a member of the Mid-Atlantic Association of Forensic Scientists and the Clandestine Laboratory Investigative Chemists Association.

4. On May 22, 1997, I conducted an analysis of 3.2 grams of a green, leafy substance contained in two clear plastic bags which had been marked as Exhibit 11. My analysis of the substances contained in the bags marked as Exhibit 11 identified the presence of marijuana.

5. On July 3, 1997, I conducted an analysis of 3.4 grams of a green, leafy substance contained in a clear plastic bag which had been marked as Exhibit 23. My analysis of the substance contained in the bag marked as Exhibit 23 identified the presence of marijuana.

6. On August 13, 1997, I conducted an analysis of 3.4 grams of a green, leafy substance contained in a clear plastic bag which had been marked as Exhibit 33. My analysis of the substance contained in the bag marked as Exhibit 33 identified the presence of marijuana.

7. On September 15, 1997, I conducted an analysis of 3.4 grams of a green, leafy substance contained in a clear plastic bag which had been marked as Exhibit 37. My analysis of the substance contained in the bag marked as Exhibit 37 identified the presence of marijuana.

8. On October 28, 1997, I conducted an analysis of 3.3 grams of a green, leafy substance contained inside a clear plastic bag which had been marked as Exhibit 41. My analysis of the substance contained in the bag marked as Exhibit 41 identified the presence of marijuana.

9. On November 21, 1997, I conducted an analysis of 3.3 grams of a green, leafy substance contained inside a clear plastic bag which was marked as Exhibit 55. My analysis of the substance contained in the bag marked as Exhibit 55 identified the presence of marijuana.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ PHYLLIS E. QUINN
PHYLLIS E. QUINN

Executed this 23 day of December 1997

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO HEADQUARTERS

C 98-0088-CAL

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE; AND
JEFFREY JONES, DEFENDANTS

[Filed: Jan. 9, 1998]

DECLARATION OF SPECIAL AGENT MARK NELSON

I, MARK NELSON, do hereby declare and say as follows:

1. I am a Special Agent with the San Francisco Field Division of the Drug Enforcement Administration ("DEA"), United States Department of Justice, and have been so employed since December 1985.

2. I have received training from the DEA and Federal Bureau of Investigation in specialized narcotic investigative matters including, but not limited to, the following: drug interdiction and detection, money laundering techniques and schemes, drug identification, and asset identification and forfeiture. This training included specialized training in the preparation of

narcotic and document search warrants for residences and businesses.

3. I have participated in numerous investigations specifically involving both the indoor and outdoor manufacture or cultivation of marijuana. In the course of these investigations, I have personally participated in the eradication of over 12,000 indoor and 5,000 outdoor marijuana plants, and the arrest of more than 200 individuals for violations of federal and state law regarding controlled substances. I also have received specialized training regarding the techniques used to grow marijuana. Based on my experience and training, I am familiar with the smell and appearance of growing and processed marijuana, as well as the smell of marijuana when it is burning. I also have participated in the obtaining and/or execution of over 150 federal and California state warrants to search a particular place or premises for controlled substances and/or related paraphernalia, indicia, and other evidence of the commission of state and/or federal felony violations of law.

4. On May 20, 1997, acting in an undercover capacity, I telephoned the Oakland Cannabis Buyer's Cooperative ("OCBC") at 510-832-5346 and spoke to an individual whom I assumed was an employee of the OCBC. I informed this individual that I had been contacted by a patient of the doctor who had been listed on Special Agent Brian Nehring's phony physician statement, who told me that the OCBC may be calling to verify that he (Special Agent Nehring, acting in an undercover capacity) was a patient of the doctor. I told this individual that I was affirming that this individual (Special Agent Nehring, acting in an undercover

capacity) was a patient of this doctor, and that this doctor had signed a physician statement to that effect.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ MARK NELSON
MARK NELSON

Executed this 8th day of January 1998

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00089 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OF ROBERT T. BONARDI

I, ROBERT T. BONARDI, declare:

1. I am a patient-member of the Oakland Cannabis Buyers' Cooperative ("OCBC"). I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. I live in Hayward, California with my wife of 53 years. I am the father of three children, and I have four grandchildren. I have owned a vacuum cleaner store for the past 20 years. I am no longer able to go to my store to work because I have cancer and am undergoing chemotherapy.

3. I was first diagnosed with cancer of the throat ten years ago. I underwent radiation therapy as part of my treatment then. At that time the doctors removed my voicebox and performed a tracheotomy. I still have a hole in my throat.

4. Two years ago I lived through prostate cancer.

5. Earlier this year the doctors discovered a tumor on the side of my neck. They removed it, but later the doctors discovered more tumors on my shoulder, chest, and neck area. Since I have already had radiation treatments, I had to undergo intensive chemotherapy for these new cancers.

6. After they started the chemotherapy treatments this year, I got really sick. The nausea was so bad I would retch whenever I thought about food or whenever anyone tried to put food in front of me. The nausea made me particularly afraid to eat because my throat condition makes it especially unpleasant if I vomit. Not only would vomit come out of my mouth, but it would also come out of my nose.

7. Over a period of about six weeks, I lost forty pounds. My wife and children became very worried about my not eating and about my dramatic weight loss.

8. I tried some medicines the doctors prescribed for me to help me with the nausea and my lack of appetite, but none of them worked for me. I took them but still I could not bring myself to eat. I was still losing weight.

9. Eventually, my daughter Judy forced me to go with her to the Oakland Cannabis Buyers Cooperative.

At first I did not want to go. It took my daughter a long time to convince me to go. I am 74 years old and I had never used marijuana before in my life.

10. The OCBC gave me papers to take to my doctor to fill out. My E.N.T. doctor from Kaiser in Fremont signed the papers. My daughter took me back to the OCBC. I bought cannabis brownies, some cannabis pills, and some cannabis banana muffins. Because of my condition I cannot smoke.

11. The first day I ate half a cannabis brownie before breakfast and nothing much happened.

12. Later that same day, I ate another half brownie and for the first time in several weeks, I felt like eating. The brownie caused my nausea to go away. I asked my wife to cook me eggs and sausage. She was so happy because it had been so long since I had asked for food. I have since regained some of the weight I lost.

13. Cannabis is the best medicine for my conditions caused by the chemotherapy treatments. In fact, it is the only medicine that has worked for me. I believe that without cannabis I would have continued to starve.

14. The OCBC has provided a safe place where I can get this life-saving medicine. If cannabis were not available through OCBC, I would be forced to go without the only medicine that has worked for me to relieve my nausea and to give me my appetite back. I would refuse to get my medicine from criminal street dealers.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 9/10/98 day of September at Oakland, California.

/s/ ROBERT J. BONARDI
ROBERT J. BONARDI

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Nos. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98-00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION

TO THIS HONORABLE COURT:

1. My name is Willie C. Beal. I am over 18 years of age and am of sound mind. I make the following statements upon my own personal knowledge of the facts stated herein. If called upon, I am willing to testify orally to such matters.

2. The Oakland Cannabis Buyers' Cooperative helps me in the following ways: Its helps me to eat. I need to eat so that I can gain weight. If I don't eat I die. Food makes me want to throw-up that's what cancer does to you. And the pain you are in, unbearable pain. It really helps! The club has kept me alive from day to day.

3. If the Oakland Cannabis Buyers' Cooperative were to close, I would suffer imminent serious harm in the following ways: I would die, I would simply die. You lose wieght [*sic*] fast with cancer. You can't eat, everything makes you sick, I'm alergic [*sic*] to everything so I have to have something everyday. I'm too old and in too much pain to try to go on the street. I live in Oakland and it is hard, very hard. I'm trying to live from day to day this is helping me to make it. Please don't take this away. It would kill me, my birthday is October 31. I will be 71 years old. If I live to make it. Please don't murder innocent victims of the club! Have some compassion! You may be in my shoes one day.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

WILLIE BEAL
Signature

WILLIE C. BEAL
Print Name

Declared and signed in Oakland, California this 15th day of October, 1998. This order is signing my death warrant as if I was a person on death row in prison who is innocent.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00089 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OF ALBERT DUNHAM

I, ALBERT DUNHAM, declare:

1. My name is Albert Dunham. I am 43 years of age, am of sound mind, and am competent to testify to the matters stated herein.

2. I am a member of the Oakland Cannabis Buyers' Cooperative. I was present at the Cooperative on May 21, 1998.

3. I was diagnosed as HIV-positive in June, 1996. As a result of my disease, I have suffered from constant nausea, fatigue, insomnia, lack of appetite, weight loss, and pain throughout my back, neck, and head. Due to these problems, I was unable to maintain my job as a

warehouse shipping and receiving clerk and am currently unemployed.

4. I have tried medicine other than cannabis to combat these problems, but they always had adverse side effects on my body, primarily by inducing vomiting. My stomach is very sensitive and does not react well to ingesting pills. At the end of 1997, my doctor prescribed cannabis for my symptoms, especially to alleviate my steady weight loss. My appetite had deteriorated so badly by this point that there were occasions when I had only one meal every two days.

5. I have been using medicinal cannabis for the past ten months, and the improvement in my overall health has been dramatic. My appetite has returned, along with some of the weight I lost, leading me to believe that continued use would allow me to return to my normal weight. In addition to my increased appetite, regular use of cannabis has alleviated the pain I feel throughout my body and generally relaxed me by reducing the anxiety and stress associated with my disease and symptoms. My insomnia has also improved.

6. Unlike other drugs I have tried for my illness, cannabis has left no lingering side effects. Using cannabis allows me to live a normal life, something I was unable to achieve prior to my doctor's prescription.

7. I live with my daughter, 27, who is supportive of my use of cannabis to fight the medical problems I have described. I have a new doctor now, and he is also supportive of my continued use of cannabis to combat my weight loss and other symptoms.

8. If I was no longer able to obtain cannabis through the OCBC, I would be forced to the streets to obtain it, which is a situation that I am emotionally and financially unprepared for. I have doubts that I would be able to obtain cannabis under those conditions. The OCBC's continued existence insures that I will have a safe, clean location that I can regularly visit to obtain the medicine I require.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 13 day of September, in Oakland, California.

/s/ ALBERT DUNHAM
ALBERT DUNHAM

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL.,
DEFENDANTS

DECLARATION OF TERRY STOGDELL

TO THIS HONORABLE COURT:

1. My name is Terry Stogdell. I am over 18 years of age and am of sound mind. I make the following statements upon my own personal knowledge of the facts stated herein. If called upon, I am willing to testify orally to such matters.

2. I suffer from the following serious medical conditions: I have severe AIDS, hemophilia, arthritis, and asthma.

3. If I did not have access to cannabis, I would suffer imminent harm in the following ways: I would not be able to eat and would waste away. The medications I take for AIDS take away my appetite and make me nauseous. When my stomach is upset I don't eat, and I might not take the medications that are vital to my treatment. Cannabis eases my pain, makes the nausea go away, and stimulates my appetite. As an appetite

stimulant, it works consistently and quickly. Cannabis relaxes my upset stomach, helps me eat, and lets me take my vital medications. Cannabis also helps relieve severe pain in my joints.

4. There is no alternative to cannabis for the effective treatment of my medical condition, because I have tried the following legal alternatives to cannabis and have found them to be ineffective, or to result in intolerable side effects: I have taken Marinol and Megace to stimulate my appetite and fight AIDS related wasting. Marinol is inconsistent in stimulating my appetite, and Megace is not effective at all. Both drugs can make me nauseous. I have taken Compazine for nausea. However, it causes painful cramps in my fingers and toes. I am currently taking Dilauded, a very strong pain medication that can cause bleeding in my joints. With cannabis, I can ease my pain while considerably reducing the amount of Dilauded that I would otherwise have to take.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct to the best of my knowledge and belief.

/s/ TERRY STOGDELL
TERRY STOGDELL

Declared and signed in Oakland, California this 27th day of April, 2000.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00088 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL., DEFENDANTS

DECLARATION OF CREIGHTON W. FROST, JR.

TO THIS HONORABLE COURT:

1. My name is Creighton W. Frost Jr. I am over 18 years of age and am of sound mind. I make the following statements upon my own personal knowledge of the facts stated herein. If called upon, I am willing to testify orally to such matters.

2. I suffer from the following serious medical conditions: I am a cancer survivor. I am post-operative for throat and shoulder cancer. I have resultant muscle loss, and I use a voice prosthesis. I also suffer from severe depression as a result of my medical condition.

3. If I did not have access to cannabis, I would suffer imminent harm in the following ways: I would suffer chronic and intense pain on the right side of my neck and chest, where I had surgery. If high quality medical cannabis were available at an affordable price, I would not need any other pain medications. Without access to cannabis, I would suffer from the constant and extreme

nausea that results from the cancer medications that I take. Medical cannabis relieves this nausea.

4. There is no alternative to cannabis for the effective treatment of my medical condition, because I have tried the following legal alternatives to cannabis and have found them to be ineffective, or to result in intolerable side effects: I currently take Oxycontin, a morphine derivative and Ultram, a synthetic narcotic for pain relief. I find both make me groggy and sleepy, and both harm my mental clarity. Both can cause constipation. I take Oxycontin and Ultram in conjunction with cannabis. When more high quality cannabis is available, I need to take less Oxycontin and Ultram. I have tried Prozac and Zoloft for fighting depression. Both of these drugs cause me to lose normal inhibitions and can make me act in dangerously inappropriate ways. Cannabis relieves my depression without side effects. I have taken Marinol to relieve the nausea that I suffer, but I find it to be ineffective.

5. Being unable to obtain medical cannabis from the Oakland Cannabis Buyers' Cooperative has effected my health and well-being in the following ways: It has resulted in my suffering from poor health overall, extreme depression, more pain, and bouts of anger.

I declare under penalty of perjury under the laws of the State of California that the forgoing is true and correct to the best of my knowledge and belief.

/s/ CREIGHTON W. FROST JR.
CREIGHTON W. FROST JR.

Declared and signed in Oakland, California this 29th day of April, 2000.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00089 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OF HAROLD SWEET

I, HAROLD SWEET, declare:

1. I am a patient-member of the Oakland Cannabis Buyers' Cooperative (the "Cooperative"). I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. I am a retired school teacher. I taught botany and biology in a junior college. I am sixty-four years old. I suffer from glaucoma.

3. I was first diagnosed with glaucoma in 1994. At that time my field of vision was deteriorating rapidly. Also, I experienced intense pain from the build up of

pressure in my eyes. I also experienced pain when I was exposed to bright lights. I often had to go lie down in a dark room just to try to escape the pain.

4. Prior to my eye disease, I was never an illicit drug user or somebody who used marijuana. Personally, I have actually always been opposed to the so-called "pot-heads" in our society.

5. Since my glaucoma diagnosis I have been taking medical cannabis for my condition. This medicine has worked wonders. First, the medical cannabis keeps my eye pressure down. When I medicate with cannabis, the pain goes away, and I no longer experience intense pain from bright lights.

6. Second, much to my doctor's amazement, not only has my field of vision not deteriorated any further since I have been medicating with cannabis, but it may have even improved. Also, my doctor has told me that my optic nerve is in good shape. I attribute this to the cannabis treatment.

7. There is a very strong possibility that I would be blind if I did not take cannabis for my glaucoma.

8. Though I have tried other drugs and treatments for my glaucoma, no other drug or treatment works for me.

9. According to my doctor's suggestion, I have been modulating my use of medical cannabis. Currently, I smoke a little bit of cannabis three times a day. This is the only way I know how to get through the day without pain. It is also the only way I know how to maintain my vision.

10. The Cooperative has provided a safe place where I can get this life-saving medicine. If cannabis were not available through the Cooperative, I would be forced to go without the only medication that has worked to alleviate my glaucoma.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 10 day of September at Oakland, California.

/s/ HAROLD SWEET
HAROLD SWEET

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No. C 97-0139 FMS

DR. MARCUS CONANT, DR. DONALD NORTHFELT, DR. ARNOLD LEFF, DR. DEBASISH TRIPATHY, DR. NEIL FLYNN, DR. STEPHEN FOLLANSBEE, DR. ROBERT SCOTT, III, DR. STEPHEN O'BRIEN, DR. MILTON ESTES, DR. VIRGINIA CAFARO, DR. HOWARD MACCABEE, JO DALY, KEITH VINES, JUDITH CUSHNER, VALERIE CORRAL, DANIEL KANE, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED; BAY AREA PHYSICIANS FOR HUMAN RIGHTS; AND BEING ALIVE: PEOPLE WITH AIDS/HIV ACTION COALITION, INC., PLAINTIFFS

v.

BARRY R. MCCAFFREY, AS DIRECTOR, UNITED STATES OFFICE OF NATIONAL DRUG CONTROL POLICY; THOMAS A. CONSTANTINE, AS ADMINISTRATOR, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; JANET RENO, AS ATTORNEY GENERAL OF THE UNITED STATES; AND DONNA SHALALA, AS SECRETARY OF HEALTH AND HUMAN SERVCIES, DEFENDANTS

March 21, 1997
[Original Filed: Feb. 14, 1997]

DECLARATION OF MARCUS A. CONANT, M.D.

I, Dr. Marcus A. Conant, declare as follows:

1. I am a physician licensed to practice in the State of California and a clinical professor of dermatology at the University of California Medical Center in San

Francisco ["UCSF"], where I have taught for more than 30 years. I am also Medical Director of the largest private HIV/AIDS practice in the San Francisco Bay Area. Since establishing that practice, my colleagues and I have treated some 5,000 HIV-infected men and women, and we currently provide care for approximately 3,000 AIDS patients in both our clinic and our research facility.

2. I received a bachelor's degree in 1957 and a doctorate in 1961, both from Duke University. I subsequently completed an internship in internal medicine at the Duke University Medical Center (1961-1962), and a residency in dermatology at UCSF in San Francisco (1964-1967). I received further training at the School of Aerospace Medicine in San Antonio, Texas, and served in the United States Air Force from 1962 to 1964, as both a Medical Officer and a Flight Surgeon. I continued to serve as an Air Force Reserve Officer until 1967.

3. Since joining the UCSF faculty as a Clinical Instructor in 1967, I have held numerous positions, including Assistant Clinical Professor, Associate Clinical Professor, and Clinical Professor of Dermatology, a post I have held since 1984. I was Chief of both the Dermatology Clinic and the Dermatology Inpatient Service from 1967 through 1970, Co-Director of the Medical Center's Kaposi's Sarcoma Clinic (1981-1985), and Director of its AIDS Clinical Research Center (1983-1985). I am currently an Adjunct Professor at its Mount Zion Medical Center as well.

4. Throughout my career, I have also been a consultant to numerous agencies and service providers, both public and private, including San Francisco Gen-

eral Hospital, the U.S. Public Health Service Hospital, UC Medical Center's Director of Hospitals and Clinics, and the California State Assembly Ways and Means Committee's AIDS Task Force. I have been appointed to similar task forces and committees of the Fifth Congressional District, the California State Department of Health Services, the California Medical Association, the San Francisco Medical Society, the American Academy of Dermatology, and the City of San Francisco. In 1983, I represented the United States at the World Health Organization meeting on AIDS. I served as Medical Director of the National Public Health Project Against AIDS for several years. I am currently a member of United States Senator Dianne Feinstein's AIDS Committee.

5. I have authored and co-authored some 70 articles in scholarly and professional journals, most of which deal with the diagnosis and treatment of AIDS and AIDS-related conditions. My work has been published in the Journal of the American Medical Association, New England Journal of Medicine, Western Journal of Medicine, Journal of the American Academy of Dermatology, Journal of Infectious Disease, American Journal of Clinical Pathology, Journal of Clinical Immunology, Journal of Osteopathic Medicine, American Journal of Oral Medicine, Public Health Reports, Clinical Research, American Journal of Pathology, and The Lancet. My colleagues and I have contributed chapters to medical textbooks, research publications, clinical protocols and conference reports. I am a frequent presenter at national and international conferences and congresses.

6. Many of the therapies used in the treatment of AIDS-related conditions can cause symptoms and medical complications which themselves are physically painful and medically dangerous. The most frequently cited example is chemotherapy, which is often a first-line treatment in the aggressive treatment of cancer. Chemotherapy has also been used in the treatment of several common AIDS-related conditions, including lymphoma and Kaposi's sarcoma. Chemotherapy—administering medications such as adriamycin, fluorouracil, cytotoxin and methotrexate, usually in combination—has proven to be highly effective in the treatment of many cancers, extending lives and relieving the symptoms of many individuals whose conditions were once considered hopeless. These medications have been approved by the FDA. Nonetheless, chemotherapy protocols used in the treatment of cancer often cause nausea and retching which is sometimes thoroughly disabling. They can result in severe weight loss, which itself has troubling implications not only for the efficacy of the treatment, but for a patient's health generally. The medications are indeed toxic. Administration of these drugs always includes considering potential adverse effects, advising the patient of the risks and providing information and treatment to reduce harmful or undesirable side effects. Acknowledgment and clinical treatment of those effects are standard and necessary parts of the chemotherapy protocols.

7. Other drugs frequently prescribed in the treatment of AIDS-related conditions have the potential to cause adverse medical conditions. Among them are AZT, ddI, ddC and d4T, all of which are approved by the FDA. More recently, physicians have prescribed a

class of drugs known as "protease inhibitors," often in combination with other medications. The results have been very promising. Physicians are seeing positive clinical results, and laboratory findings (blood tests) show remarkable improvements. Many patients report great relief from physical suffering. These drugs are now approved by the FDA. One common AIDS-related condition is wasting syndrome, which undermines both the immune system generally and a patient's ability to withstand the effects of other therapies. The FDA has approved the use of Somatropin (human growth syndrome), as well as Megace and Marinol, to reverse the disabling effects of wasting syndrome.

8. As with all medications, further research is essential to our understanding of these medications. As research continues, the use of these medications (*e.g.*, dosages, means of ingestion, combination therapies) will be refined to maximize the potential for treatment and minimize adverse reactions. That is the very nature of research. There are always risks. As scientists, we identify those risks and provide information to reduce and ultimately eliminate those risks. As healers, we advise our patients accordingly and work with them to address their individual medical needs. Caution and candor are essential to maintaining scientific integrity and providing effective treatment.

9. Medical marijuana has been used extensively by physicians throughout the United States in the treatment of cancer and AIDS patients. It stimulates the appetite and promotes weight gain, in turn strengthening the body, combating chronic fatigue, and providing the stamina and physical well-being necessary to endure or withstand both adverse side effects of

ongoing treatment and other opportunistic infections. It has been shown effective in reducing nausea, neurological pain and anxiety, and in stimulating appetite. When these symptoms are associated with (or caused by) other therapies, marijuana has been useful in facilitating compliance with more traditional therapies. It may also allow individual patients to engage in normal social interactions and avoid the despair and isolation which frequently accompanies long-term discomfort and illness. In glaucoma patients, marijuana has been effective in decreasing inter-ocular pressure. The evidence behind these findings is both scientific and anecdotal. The research in this area has been documented and published in the leading scientific journals, including the New England Journal of Medicine and Annals of Internal Medicine.

10. In my practice, marijuana has been of greatest benefit to patients with wasting syndrome. I do not routinely recommend marijuana to my patients, nor do I consider it the first line of defense against AIDS-related symptoms. However, for some patients, marijuana proves to be the only effective medicine for stimulating appetite and suppressing nausea, thus allowing the AIDS patient to recover lost body mass and become healthier. Likewise, for some of my patients undergoing chemotherapy, when conventional drugs fail to relieve the severe nausea and vomiting, I often find that marijuana provides the patient with the ability to eat and to tolerate aggressive cancer treatments. As with any medication, I am aware of the potential for abuse and I am cautious in the information I provide. Some of my patients are using marijuana, which I learn in the course of my treatment. I advise those patients of the risks that marijuana may pose. In

some instances, I have counseled patients to discontinue or decrease their use of marijuana. In patients with a history of substance abuse, I am especially vigilant in recommending caution. Physicians have always been held to that standard, whether the medication is Valium, morphine, Xanax, or marijuana. Safeguards to decrease the incidence and effects of substance abuse are already in effect. Medical practices in prescribing and recommending all treatments are monitored and subject to professional and legal guidelines.

11. It is the sanctity of the doctor-patient relationship that enables this counseling and guidance to take place. The unique nature of that relationship has been recognized throughout history. Legally, ethically and clinically, a physician has unique duties to a patient in his or her care. When I treat a patient with a potentially terminal condition, I provide the information and treatment that can literally determine whether my patient lives or dies. My duty is to provide accurate and complete information and treat each patient according to his or her individual symptoms, medical history and clinical responses. Each patient's medical needs are unique, as are his/her responses to specific therapies. Confidential communication is essential to this process.

12. As a physician responsible for the care and well-being of my patients, I cannot ignore information which might affect my assessment of a patient's condition or assist me in providing the best care possible. If I have knowledge that a patient is smoking marijuana, I would be seriously remiss if I failed to address the medical consequences with that patient. If I have information

that limited use of marijuana may provide relief from disabling symptoms, I feel duty-bound to provide that information. If I believe, in my clinical judgment, that the risks to that patient may be reduced if the marijuana is ingested by means other than smoking (*e.g.*, by eating baked goods or drinking a tea with marijuana infusion), I have a duty to provide that information as well. That knowledge is based on my scientific knowledge, clinical judgment, and common sense.

13. My knowledge and clinical judgment are informed by all credible sources, including the federal Food and Drug Administration. I was one of the principal investigators of an FDA-supervised trial conducted by Unimed, Inc. on the safety and efficacy of Marinol as an appetite stimulant in HIV/AIDS patients suffering from wasting syndrome. Marinol is a form of THC, one of the key active components of marijuana; it is essentially a marijuana extract. It was approved by the FDA five years ago, and has been widely prescribed by physicians treating both AIDS and cancer patients.

14. The current edition of the Physician's Desk Reference, the most widely-used and comprehensive authority on prescription medications, states that:

> Marinol (dronabinol) is indicated for the treatment of:
>
> 1. anorexia associated with weight loss in patients with AIDS; and
> 2. nausea and vomiting associated with cancer chemotherapy in patients who have failed to

> respond adequately to conventional antiemetic treatments.[1]

Stedman's Medical Dictionary, another highly respected and widely-used reference work, as part of its definition of "cannabis," includes the following:

> C[annabis] was formerly used as a sedative and analgesic; now available for restricted use in management of iatrogenic[2] anorexia, especially that associated with oncologic chemotherapy and radiation therapy.[3]

I am aware of no medical report that would indicate serious adverse effects arising from the clinical use of Marinol.

15. I am aware, however, that Marinol (like any medication) is not effective in treating all patients. In some cases, the reason is simple: Marinol is taken orally, in pill form. Patients suffering from severe nausea and retching cannot tolerate the pills and thus do not benefit from the drug. There are likely other reasons why smoked marijuana is sometimes more effective than Marinol. The body's absorption of the chemical may be faster or more complete when inhaled. Means of ingestion is often critical in understanding treatment efficacy. Research has revealed, for example, that insulin, which is critical in the treatment of diabetes, is rendered ineffective when taken orally.

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[1] *Physicians' Desk Reference*, 50th Edition (1996: Medical Economics), p. 2232.

[2] "Iatrogenic" conditions are those which result from medical treatments or procedures, such as chemotherapy-related nausea or weight loss.

[3] Spraycar, M. (ed.), *Stedman's Medical Dictionary*, 26th edition (1995: Williams & Wilkins), p. 269.

Medications commonly used to treat asthma and lung infections are routinely administered through inhalers. Marinol is not currently available in any form other than pills. These are scientific facts which inform my clinical practice. I cannot ignore them or deprive my patients of that knowledge.

16. I am aware that federal government officials have issued threats of criminal, civil and administrative sanctions against physicians who recommend the use of marijuana or counsel and advise patients regarding the clinical risks and benefits of marijuana. They have repeatedly stated that providing counsel and advice regarding the clinical use of marijuana is a violation of federal law. I see these public pronouncements as a threat to the integrity of my medical practice. While there are certainly limitations on my ability to obtain or prescribe medications, I cannot ethically withhold information or scientific data which may be of benefit to my patients. If I am prohibited from advising my patients on any matter affecting their health, I am unable to exercise clinical judgment and provide effective treatment.

17. Such interference in my communications with individual patients can do immeasurable damage to my relationship with specific patients, thereby undermining my ability to provide effective treatment generally. Without the element of mutual trust and protected confidentiality, many of my patients will be unable or unwilling to provide me with information essential to my medical assessment. As a result, I am disarmed in my struggle against illness and suffering. They are deprived of basic medical information which could inform their behavior and relieve their disabilities. In

light of the recent government threats, I have already limited my discussions with patients and directed my staff (including other physicians) to use extreme caution when obtaining medical histories or answering patient inquiries about marijuana. Even this degree of wariness and apprehension has a chilling effect on my rapport with patients. They see me as part of their fight for life. Government threats disarm me in that struggle, and it is my patients who will ultimately suffer.

18. I have already stated that marijuana has proven effective in addressing many symptoms caused by medically prescribed treatments. The adverse affects of these therapies are particularly troubling to both the patient and the physician. In my practice, I frequently recommend treatments which, in the short term, may result in increased discomfort and visible suffering. They may also have adverse implications for the patient's long-term health. I cannot, in good faith, recommend these procedures and medications without a professional commitment to decrease, prevent or reduce the effects of these conditions.

19. Failure to consider every possible means of alleviating adverse side effects has very serious implications. When a patient can no longer tolerate the adverse consequences, she or he will cease treatment. I have seen it many times in my own practice and my colleagues report it consistently. It is a tragic fact which we monitor and assess constantly. In the case of chemotherapy and many AIDS medications, terminating treatment can mean an early and often painful death. It results in hopelessness where there should be, or could be, hope. As a scientist and a healer,

preventable suffering and unnecessary despair are unacceptable.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct to the best of my knowledge, and that this declaration was executed this 14 day of February, 1997 in San Diego, California.

/s/ MARCUS A. CONANT, M.D.
MARCUS A. CONANT. M.D.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Case No. C 97-0139 FMS

DR. MARCUS CONANT, DR. DONALD NORTHFELT, DR. ARNOLD LEFF, DR. DEBASISH TRIPATHY, DR. NEIL FLYNN, DR. STEPHEN FOLLANSBEE, DR. ROBERT SCOTT, III, DR. STEPHEN O'BRIEN, DR. MILTON ESTES, DR. VIRGINIA CAFARO, DR. HOWARD MACCABEE, JO DALY, KEITH VINES, JUDITH CUSHNER, VALERIE CORRAL, DANIEL KANE, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, BAY AREA PHYSICIANS FOR HUMAN RIGHTS; AND BEING ALIVE: PEOPLE WITH AIDS/HIV ACTION COALITION, INC., PLAINTIFFS,

v.

BARRY R. MCCAFFREY, AS DIRECTOR, UNITED STATES OFFICE OF NATIONAL DRUG CONTROL POLICY; THOMAS A. CONSTANTINE, AS ADMINISTRATOR, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, JANET RENO, AS ATTORNEY GENERAL OF THE UNITED STATES, AND DONNA SHALALA, AS SECRETARY OF HEALTH AND HUMAN SERVICES, DEFENDANTS

March 21, 1997
[Original Filed: Feb. 14, 1997]

DECLARATION OF
HOWARD D. MACCABEE, PH.D., M.D

I, DR. HOWARD D. MACCABEE, declare as follows:

1. I am a physician licensed to practice in the State of California. I have been Medical Director of the Radiation Oncology Center in Walnut Creek, California, for 17 years. I am also an Assistant Clinical Professor of Medicine at the University of California at San Francisco ("UCSF").

2. I received a B.S. from Purdue University in Lafayette, Indiana, in 1961. I received a Ph.D from the University of California at Berkeley in 1966. My dissertation research was on radiation biophysics. After extensive research in the areas of physics and medicine, I attended the University of Miami School of Medicine, where I earned a M.D. in 1975. I then completed my Internship at UCSF in 1976, followed by a three-year Residency in radiation oncology, also at UCSF.

3. I am board certified in therapeutic radiology and am a member of several professional societies. I have published 25 articles on diverse scientific and medical topics.

4. I have also studied the ethical aspects of the doctor-patient relationship and am on the bioethics committees of John Muir Medical Center and the Alameda-Contra Costa County Medical Association. I have chaired symposia on this issue between 1988 and 1994 in Contra Costa County.

5. In my practice, I commonly use radiation therapy to treat the whole spectrum of solid malignant tumors. Radiation therapy is often used after surgery or chemotherapy, as a second stage in treatment. Sometimes, however, radiation therapy is used concurrently with

chemotherapy, or even as the first or only modality of treatment.

6. I treat approximately 20 patients each day and provide follow-up care and/or consultation with another 5 or so patients a day. I currently have approximately 2,000 patients in various stages of follow-up to their initial treatment. Most of these are long-term survivors.

7. Because of the nature of some cancers, I must sometimes irradiate large portions of my patients' abdomens. Such patients often experience nausea, vomiting, and other side effects. Because of the severity of these side effects, some of my patients choose to discontinue treatment altogether, even when they know that ceasing treatment could lead to death.

8. During the 1980s, I participated in a state-sponsored study of the effects of marijuana and THC (an active ingredient in marijuana) on nausea. It was my observation during this time that some patients smoked marijuana while hospitalized, often with the tacit approval of physicians. I also observed that medical marijuana was clinically effective in treating the nausea of some patients.

9. During my career as a physician. I have witnessed cases where patients suffered from nausea or vomiting that could not be controlled by prescription anti-emetics. I frequently hear similar reports from colleagues treating cancer and AIDS patients. As a practical matter, some patients are unable to swallow pills because of the side effects of radiation therapy or chemotherapy, or because of the nature of the cancer

(for instance, throat cancer). For these patients, medical marijuana can be effective form of treatment.

10. I occasionally have patients who inquire about the use of medical marijuana. I have always considered it my ethical duty as a physician to provide every patient with the full truth as I know it. This duty includes informing patients about treatment options that I personally do not provide. For example, although I do not prescribe chemotherapy, it is my ethical obligation to discuss this treatment option with patients who are also considering undergoing radiation treatment. Because of the threats by federal officials against physicians who provide information to patients regarding the potential risks or benefits of the medical use of marijuana, I have had to reexamine this basic ethical principle for the first time in my professional career.

11. Due to fear caused by the threats of federal officials, I feel compelled and coerced to withhold information, refuse to make recommendations, and modify for non-clinical reasons my advice to patients regarding use of medical marijuana. Since the threats, I have not had any patients ask about medical marijuana. When I do receive such an inquiry, however, I will temper what I say to avoid the risk of government sanction. Based on my years of practice, I am concerned that my reticence in providing information will adversely affect the doctor-patient relationship, a result which is both regrettable and ethically substandard.

12. I understand that one of the reasons behind the threats is to deter physicians who may inappropriately recommend the use of medical marijuana. The threat of abuse in this context is no greater than the threat

posed by doctors who misprescribe or othewise act irresponsibly with regard to any drug. There will always be a small number of doctors who behave irresponsibly; those individual doctors should certainly be sanctioned, but not at the expense of the ability of responsible doctors to provide important medical information to their patients.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed at Walnut Creek, California, this 14th day of February, 1997.

/s/ HOWARD D. MACCABEE
HOWARD D. MACCABEE

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-0085 CRB
C 98-0086 CRB
C 98-0087 CRB
C 98-0088 CRB
C 98-0089 CRB
C 98-0245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANTS
AND RELATED ACTIONS

DECLARATION OFJOHN P. MORGAN, M.D.

I, JOHN P. MORGAN, declare:

1. I am a medical doctor and Professor of Pharmacology at the City University of New York Medical School. I have personal knowledge of the facts stated herein, and if called as a witness, I could and would testify competently as to them.

2. I am co-author of the book entitled "Marijuana Myths, Marijuana Facts—A Review of the Scientific Evidence," published in 1997.

3. Marijuana, also known as cannabis, has many proven medical uses. Medical cannabis reduces nausea and vomiting induced by cancer chemotherapy, stimu-

lates appetite and promotes weight gain in AIDS patients, reduces intraocular pressure in people suffering from glaucoma, reduces muscle spasticity in patients with neurological disorders, spinal cord injuries, and multiple sclerosis. Furthermore, patients and physicians have reported that smoked marijuana also provides relief from migraine headaches, depression, seizures, and pain.

4. Recent studies have shown that cannabinoids may also be useful for other neurological disorders, such as stroke.

5. There are no reasonable legal alternatives to medical cannabis for many patients. Delta-9-THC is the main active ingredient in marijuana. While synthetic THC is available in capsule form, it is not nearly as effective as smoked marijuana for many patients. For people suffering from nausea and vomiting, who are unable to swallow and hold down a pill, smoking marijuana is often the only reliable way to deliver THC to the body. Smoking marijuana delivers THC quickly, providing relief in a few minutes, compared to an hour or more when THC is swallowed.

6. Smoking marijuana not only delivers THC to the bloodstream more quickly than swallowing synthetic THC, but smoking delivers most of the THC inhaled. When synthetic THC is swallowed, 90 percent or more of it never reaches sites of activity in the body as a result of the body's extensive metabolism of swallowed THC.

7. Another problem with swallowed THC is that it effects vary considerably, both from one person to

another and in the same person from one episode of use to another. Further, because the onset of effect is an hour or more, patients using synthetic THC have difficulty achieving just the effective dose. Moreover, when THC is swallowed, the effects last longer (up to six hours) compared to one or two hours when marijuana is smoked. Thus, smoking marijuana is a more flexible route of administration than swallowing because smoking allows patients to adjust their dose to coincide with the rise and fall of symptoms. For people suffering from nausea and vomiting from AIDS or cancer chemotherapy, smoked marijuana provides rapid relief with lower overall doses of THC.

8. The psychoactive side effects of swallowed synthetic THC may be more intense than those that occur from smoking, thereby increasing the likelihood of adverse psychological reactions. This occurs because the liver actually produces, in high concentration, an active metabolite.

9. Smoking is a highly unusual way to administer a drug. Many drugs could be smoked, but there is no good reason to do so because oral preparations produce adequate blood concentrations. This is not the case with THC. Inhaling is a better route of administration than swallowing. Inhaling is about equal in efficiency to intravenous injection, and considerably more practical.

10. "Cannabis buyers' cooperatives" are the best and safest way for patients to obtain medical cannabis. Patients who rely on the criminal street markets to obtain marijuana necessarily acquire cannabis of unknown potency and purity. For example, marijuana purchased from a street dealer may contain fungal spores, which may be deadly for AIDS patients who have suppressed immune systems. As a result of the dangers of obtaining marijuana from the criminal market, some patients who need the drug may choose to forego their medication.

11. The Drug Enforcement Administration's own administrative law judge, Francis L. Young, concluded not only that marijuana's medical utility had been adequately demonstrated by the evidence, but that marijuana had been shown to be "one of the safest therapeutically active substances known to man." The DEA administrator ignored this opinion when he decided to maintain marijuana as a Schedule I drug.

12. For many patients medical cannabis is necessary to avert imminent and often life-threatening harm. For many patients, such as those undergoing intensive chemotherapy or experiencing AIDS-related "wasting syndrome," medical cannabis saves their lives. For patients suffering from glaucoma, medical cannabis may save their vision. For patients suffering neurological disorders resulting from spinal cord injuries and multiple sclerosis, medical cannabis may enable them to physically cope in society, to go on with their lives and to endure pain.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 13th day of August at New York, New York.

JOHN P. MORGAN
JOHN P. MORGAN, M.D.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 98-00085 CRB
C 98-00086 CRB
C 98-00087 CRB
C 98-00088 CRB
C 98 00089 CRB
C 98 00245 CRB

UNITED STATES OF AMERICA, PLAINTIFF

v.

CANNABIS CULTIVATOR'S CLUB, ET AL., DEFENDANT AND RELATED ACTIONS

DECLARATION OF LESTER GRINSPOON, M.D., IN SUPPORT OF DEFENDANTS' RESPONSE TO SHOW CAUSE ORDER

I, LESTER GRINSPOON, M.D., declare:

1. I am an Associate Professor of Psychiatry, at Harvard Medical School in Boston, Massachusetts, where I have taught for more than 35 years. I am also Editor of The Harvard Mental Health Letter. My area of research is psychoactive drugs. I am particularly interested in the medicinal properties of cannabis. If called as a witness, I could and would testify competently to the facts set forth below. I have attached a

copy of my *Curriculum Vitae* as Exhibit A. For the Court's convenience, where appropriate I have provided footnotes referencing the sources upon which I have relied.

2. I received a bachelor's degree in 1951 from Tufts College. I received a doctorate in 1955 from Harvard Medical School. I subsequently completed an internship in Medicine at Beth Israel Hospital in Boston, Massachusetts (1955-1956), and a residency in psychiatry at Massachusetts Mental Health Center (1958-1961). I received further training as a field instructor for the National Cancer Institute in Los Angeles, California (1956-1958).

3. Since joining the Harvard Medical School faculty in 1973, I have held numerous positions, including Associate Clinical Professor, Assistant Clinical Professor, and Senior Psychiatrist for the Massachusetts Mental Health Center. My other research and teaching appointments include, Assistant in Medicine for University of Southern California School of Medicine (1956-1958), Director of the Clinical Research Center for Massachusetts Mental Health Center (1961-1968), Consultant in Psychiatry and Research for Boston State Hospital (1963-1970) and an Examiner for the American Board of Psychiatry and Neurology (1969-present). I have also held several positions for the American Psychiatric Association such as Vice-Chairperson (1975-1977) and Chairperson for the Council on Research (1977-1979), Vice-Chairperson (1979-1980) and Chairperson for Scientific Program Committee (1980-1984).

4. I serve on several professional and community boards. These include many years as a member of the Beneficial Plant Research Association (1980-1984), the Drug Policy Foundation (1987-present), Physicians for Human Rights (1986-present), the Drug Research Group (1995-present), and Scientific and Policy Advisors of the American Council on Science and Health (1997-present). I recently served as Chairperson for the Board of Directors for the National Organization for the Reform of Marihuana Laws (1993-1995). I was also a faculty member for the Zinberg Center for Addiction Studies in Cambridge, Massachusetts (1993-1996). I am currently on several Editorial Boards, including editor for the Harvard Mental Health Letter (1984-present), the Journal of Social Pharmacology (1985-present), and Addiction Research (1991-present).

5. I have testified before the National Marijuana Commission Subcommittee of the Senate Small Business Committee in 1972, the House Select Committee on Narcotics in 1977, 1979 and 1989, the Controlled Substances Advisory Committee, the Drug Abuse Research Advisory Committee in 1978, the Senate Judiciary Committee in 1980, and the House Judiciary Committee, Sub-Committee on Crime in 1997. I am also a frequent presenter at national and international conferences.

6. I have authored and co-authored some 154 articles in scholarly and professional journals, most of which deal with clinical comparisons of drug therapies. I have contributed chapters of medical textbooks, research publications, clinical protocols and conference reports. My work has been published in the *Journal of Clinical Endocrinology and Metabolism, New England Journal*

of Medicine, Journal of the National Cancer Institute, Mental Patients in Transition, Science Digest, Archives of General Psychiatry, Comprehensive Psychiatry, Clinical Medicine, Journal of Psychiatric Research, Psychosomatic Medicine, Diseases of the Nervous System, American Journal of Psychiatry, Scientific America, Psychopharmacologia, International Journal of Psychiatry, Encyclopedia of Science and Technology, International Narcotic Report, New York Law Journal, Journal of Consulting and Clinical Psychology, Drug Therapy, World Journal of Psychosynthesis, Medical Tribune, Contemporary Drug Problems, Social Science and Medicine, Villanova Law Review, Congressional Digest, Biological Psychiatry, The Sciences, Journal of Ethnopharmacology, Handbook on Drug Abuse, The Hastings Center Report, Harvard Mental Health Letter, Harper's, Nova Law Review, New Harvard Guide to Psychiatry, Journal of State Government, Cancer Treatment & Marijuana Therapy, Journal of Drug Issues, North Carolina Journal of International Law & Commercial Regulation, Encyclopedia of Human Biology, Drugs, Society and Behavior, Journal of American Medical Association, University of West Los Angeles Law Review, and *Journal of Psychoactive Drugs.*

7. I have authored and co-authored some 13 books, several of which deal with the history and medical use of cannabis. These books include *Marihuana Reconsidered* (Harvard University Press, 2d ed. 1977), *Psychedelic Drugs Reconsidered* (Basic Books, 2d ed. 1981), *Psychedelic Reflections* (Human Sciences Press, 1982), *The Long Darkness: Psychological and Moral Perspectives on Nuclear Winter* (Yale University

Press, 1986), and *Marihuana, The Forbidden Medicine* (Yale University Press, Revised Edition 1997).

8. Based on my research, I have found that cannabis is remarkably safe. Although not harmless, it is surely less toxic than most of the conventional medicines it could replace if it were legally available. Despite its use by millions of people over thousands of years, cannabis has never caused an overdose death. The most serious concern is respiratory system damage from smoking, but that can easily be addressed by increasing the potency of cannabis and by developing the technology to separate the particulate matter in marijuana smoke from its active ingredients, the cannabinoids (prohibition, incidentally, has prevented this technology from flourishing). Once cannabis regains the place in the U.S. Pharmacopoeia that it lost in 1941 after the passage of the Marihuana Tax Act (1937), it will be among the least toxic substances in that compendium. Right now the greatest danger in using cannabis medically is the illegality that imposes a great deal of anxiety and expense on people who are already suffering.

9. I have done extensive research on the history of the use of cannabis for medical purposes, as well as its legal regulation in the United States. The marijuana, cannabis, or hemp plant is one of the oldest psychoactive plants known to humanity. A native plant of central Asia, cannabis may have been cultivated as much as ten thousand years ago. It was certainly cultivated in China by 4000 B.C. and in Turkestan by 3000 B.C. It has long been used as a medicine in India, China, the Middle East, Southeast Asia, South Africa, and South America. The first evidence of the medicinal

use of cannabis was published during the reign of the Chinese Emperor Chen Nun five thousand years ago. Cannabis was recommended for, among other things, malaria and rheumatic pains. Another Chinese herbalist recommended a mixture of hemp, resin, and wine as an analgesic during surgery. Hemp was also noted as a remedy by Galen and other physicians of the classical and Hellenistic eras, and it was highly valued in medieval Europe.

10. Between 1840 and 1900, more than one hundred papers on the therapeutic uses of cannabis were published in American and European medical journals. It was recommended as an appetite stimulant, muscle relaxant, analgesic, sedative, anticonvulsant, and as a treatment for opium addiction. A professor at the Medical College of Calcutta, W.B. O'Shaughnessy, was the first Western physician to observe the use of cannabis as a medicine. He gave cannabis to animals, satisfied himself that it was safe, and began to use it with patients suffering from rabies, rheumatism, epilepsy, and tetanus. In a report published in 1839, he wrote that he had found tincture of hemp (a solution of cannabis in alcohol, taken orally) to be an effective analgesic. He was also impressed with its muscle relaxant properties and called it "an anticonvulsive remedy of the greatest value." In 1890, J.R. Reynolds, a British physician, summarized thirty years of experience with *Cannabis indica*, finding it valuable in the treatment of various forms of neuralgia, including tic douloureux (a painful facial neurological disorder), and added that it was useful in preventing migraine attacks. He also found it useful for certain kinds of epilepsy, for depression, and sometimes for asthma and dysmenorrhea.

11. The medical use of cannabis was in decline by 1890. It was believed that the potency of cannabis preparations was too variable, and that individual responses to orally ingested cannabis seemed erratic and unpredictable. Another reason for the neglect of research on the analgesic properties of cannabis was that the greatly increased use of opiates after the invention of the hypodermic syringe in the 1850s allowed soluble drugs to be injected for faster pain relief; hemp products are insoluble in water and so cannot easily be administered by injection. Toward the end of the nineteenth century, the development of such synthetic drugs as aspirin, chloral hydrate, and barbiturates, also contributed to the decline of cannabis as a medicine. But these new drugs had, and still have today, striking disadvantages. More than a thousand people die from aspirin-induced bleeding each year in the United States, and barbiturates are, or course, far more dangerous.

12. Cannabis use in the United States was particularly a matter of state or federal regulation until 1915, when the first state, California, prohibited marijuana possession or sale. In 1930, the year in which the Federal Bureau of Narcotics was founded, only sixteen states had laws prohibiting the use of cannabis. In contrast, by 1937, nearly every state had adopted legislation outlawing cannabis. Sociologists have speculated that pressure from the liquor lobby figured among the more subtle factors in this sudden legal onslaught. More important, lack of scientific understanding concerning the effects of cannabis enabled the unsubstantiated statements of the Federal Bureau of Narcotics to go substantially unchallenged. The Marihuana Tax Act of 1937 was the culmination of a series of

efforts on the part of the Federal Bureau of Narcotics to generate anti-marijuana legislation.

13. One might have expected physicians looking for better analgesics and hypnotics to turn to cannabinoid substances, but the Marihuana Tax Act of 1937 undermined any such experimentation. The Marihuana Tax Act of 1937 imposed a transfer tax upon certain dealings in marijuana. The Marihuana Tax Act of 1937 provided that anyone who imports, manufactures, produces, compounds, sells, deals in, dispenses, prescribes, administers, or gives away marijuana was required to register, record transactions and pay special taxes depending on the defined purposes. Those who failed to comply were subject to large fines or prison for tax evasion. Although, it was ostensibly designed to prevent nonmedical use of cannabis, the Marihuana Tax Act of 1937 made cannabis so difficult to obtain, that cannabis was removed from the United States Pharmacopoeia and National Formulary in 1941. The Boggs Act of 1951 established mandatory prison terms and large fines for violation of any federal drug law, and the Narcotic Control Act of 1956 strengthened those penalties.

14. In the 1960s, however, the public began to rediscover the medical value of cannabis, as letters appeared in lay publications from people who had learned that it could relieve their asthma, nausea, muscle spasms, or pain and wanted to share that knowledge with readers who were familiar with the drug. Meanwhile, legislative concern about recreational use of cannabis increased, and in 1970 Congress passed the Comprehensive Drug Abuse Prevention and Control Act (also called the Controlled Substances Act), which

assigned psychoactive drugs to five schedules and placed cannabis in Schedule I, the most restrictive.

15. A few patients have been able to obtain medical cannabis legally in the last twenty years. Beginning in the 1970s, thirty-five states passed legislation that would have permitted medical use of cannabis but for the federal law. Several of those states actually established special research programs, with the permission of the federal government, under which patients who were receiving cancer chemotherapy would be allowed to use cannabis. These projects demonstrated the value of both smoked marijuana and oral THC (tetrahydrocannabinol). The FDA approved oral THC (Marinol) as a prescription medicine in 1986. In 1976, the federal government introduced the Individual Treatment Investigational New Drug program (commonly referred to as the Compassionate IND), which provided cannabis to a few patients whose doctors were willing to undergo the paperwork-burdened and time-consuming application process. About three dozen patients eventually received cannabis before the program was discontinued in 1992, and eight survivors are still receiving it—the only persons in the country for whom it is not a forbidden medicine.

16. The most effective spur to the movement for medical marijuana came from the discovery that it could prevent the AIDS wasting syndrome. It is not surprising that the Physicians Association for AIDS Care was one of the medical organizations that endorsed the California initiative prohibiting criminal prosecution of medical marijuana users.

17. I have conducted an extensive review of the literature concerning medical uses of cannabis and I am familiar with studies on the topic. Review of medical literature is a commonly used research tool. I have also studied clinically many patients who have used cannabis for the relief of a variety of symptoms; this clinical experience forms the basis of my book, *Marihuana, The Forbidden Medicine*. In my book I provide first-person accounts of the ways that cannabis alleviates symptoms of cancer chemotherapy, multiple sclerosis, osteoarthritis, glaucoma, AIDS and depressions, as well as symptoms of such less common disorders as Crohn's disease, diabetic gastroparesis, and post-traumatic stress disorder. The patient narratives illustrate not only cannabis's therapeutic properties but also the unnecessary further pain and anxiety imposed on sick people who must obtain cannabis illegally.

18. Cannabis has several uses in the treatment of cancer. As an appetite stimulant, it can help to slow weight loss in cancer patients. It may also act as a mood elevator. But the most common use is the prevention of nausea and vomiting associated with cancer chemotherapy. About half of patients treated with anticancer drugs suffer from severe nausea and vomiting, which are not only unpleasant and painful but a threat to the effectiveness of the therapy. Retching can cause tears of the esophagus and rib fractures, prevent adequate nutrition, and lead to fluid loss. Some patients find the nausea so intolerable they say they would rather die than go on. The antiemetics most commonly used in chemotherapy are metoclopramide (Reglan), the relatively new ondansetron (Zofran), and the newer granisetron (Kytril). Unfortunately, for

many cancer patients these conventional antiemetics do not work at all or provide little relief.

19. The suggestion that cannabis might be used in the treatment of cancer arose in the early 1970s when some young patients receiving cancer chemotherapy found that marijuana smoking reduced their nausea and vomiting. In one study of 56 patients who got no relief from standard antiemetic agents, 78% became symptom-free when they smoked marijuana.[1] Oral tetrahydrocannabinol (THC) has proved effective where the standard drugs were not,[2] but smoking generates faster and more predictable results because it raises THC concentration in the blood more easily to the needed level. Also, it may be hard for a nauseated patient to take oral medicine. In fact, there is strong evidence that most patients suffering from nausea and vomiting prefer smoked marijuana to oral THC.

20. Oncologists may be ahead of other physicians in recognizing the therapeutic potential of cannabis. In the spring of 1990, two investigators randomly selected more than 2,000 members of the American Society of Clinical Oncology (one-third of the membership and mailed them an anonymous questionnaire to learn their views on the use of cannabis in cancer chemotherapy. Almost half of the recipients responded. Although the

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[1] Vinciguerra, V., et al. Inhalation Marihuana as an antiemetic for cancer chemotherapy. *New York State Journal of Medicine* 1988; 88:525-527 (Attached as Exhibit B).

[2] Sallan, S.E., et al. Antiemetic effect of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy. *New England Journal of Medicine* 1975; 293:795-797 (Attached as Exhibit C).

investigators acknowledged that this group was self-selected and that there might be a response bias, their results provide a rough estimate of the views of specialists on the use of Marinol (dronabinol, oral synthetic THC) and smoked marijuana. Only 43% said the available legal antiemetic drugs (including Marinol) provided adequate relief to all or most of their patients, and only 46% said the side effects of these drugs were rarely a serious problem. Forty-four percent had recommended the illegal use of cannabis to at least one patient, and half would prescribe it to some patients if it were legal. On average, they considered smoked marijuana more effective than Marinol and roughly as safe.[3]

21. Cannabis is also useful in the treatment of glaucoma, the second leading cause of blindness in the United States. In this disease, fluid pressure within the eyeball increases until it damages the optic nerve. About a million Americans suffer from the form of glaucoma (open angle) treatable with cannabis. Glaucoma is treated chiefly with eyedrops containing beta-blockers such as timolol (Timoptic), which inhibit the activity of epinephrine (adrenaline). They are effective but may have serious side effects such as inducing depression, aggravating asthma, slowing the heart rate, and increasing the risk of heart failure. Cannabis causes a dose-related, clinically significant drop in intraocular pressure that lasts several hours in both normal subjects and those with the abnormally high ocular tension produced by glaucoma. Oral or intravenous THC has the same effect, which seems to be specific to

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[3] Doblin R. Kleiman M. Marihuana as anti-emetic medicine: a survey of oncologists' attitudes and experiences. *Journal of Clinical Oncology* 1991; 9:1275-80 (Attached as Exhibit D).

cannabis derivatives rather than simply a result of sedation. Cannabis does not cure the disease, but it can retard the progressive loss of sight when conventional medication fails and surgery is too dangerous.[4]

22. About 20% of epileptic patients do not get much relief from conventional anticomvlsant medications. Cannabis has been explored as an alternative at least since 1975 when a case was reported in which marijuana smoking, together with the standard anticonvulsants Phenobarbital and diphenylhydantoin, was apparently necessary to control seizures in a young epileptic man.[5] The cannabis derivative that is most promising as an anticonvulsant is cannabidiol. In one controlled study, cannabidiol in addition to prescribed anticonvulsants produced improvement in seven patients with grand mal convulsions; three showed great improvement. Of eight patients who received a placebo instead, only one improved.[6] There are patients suffering from both grand mal and partial seizure disorders who find that smoked marijuana allows them to lower the doses of conventional anticonvulsant medications or dispense with them altogether. Furthermore, anticonvulsants have many potentially serious side effects, including bone softening, anemia, swelling of the gums, double vision, hair loss, headaches, nausea, decreased

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[4] Hepler, R.S., et al. Ocular Effects of Marihuana Smoking. M.C. Braude, S. Szara (eds.). *The Pharmacology of Marihuana*, New York: Raven Press, 1976.

[5] Consroe, Paul F., et al. Anticonvulsant nature of Marihuana smoking. *Journal of the American Medical Association* 1975; 234-306-307. (Attached as Exhibit E).

[6] Cunha, J.M., et al. Chronic administration of cannabidiol to healthy volunteers and epileptic patients. *Pharmacology* 1980; 21:175-185. (Attached as Exhibit F).

libido, impotence, depression, and psychosis. Overdoses or idiosyncratic reactions may lead to loss of motor coordination, coma or even death.

23. There are many case reports of cannabis smokers using the drug to reduce pain: post-surgery pain, headache, migraine, menstrual cramps, and so on. Ironically, the best alternative analgesics are the potentially addictive and lethal opioids. In particular, cannabis is becoming increasingly recognized as the most effective treatment for the pain that accompanies muscle spasm which is often chronic and debilitating, especially in paraplegics, quadriplegics, other victims of traumatic nerve injury, and people suffering from multiple sclerosis or cerebral palsy. Many of them have discovered that cannabis not only allows them to avoid the risks of other drugs, but also reduces muscle spasms and tremors; sometimes they are even able to leave their wheelchairs.[7]

24. One of the most common causes of chronic pain is osteoarthritis, which is usually treated with synthetic analgesics. The most widely used of these drugs—aspirin, acetaminophen (Tylenol), and nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and naproxen—are not addictive, but they are often insufficiently powerful. Furthermore, they have serious side effects. Stomach bleeding and ulcer induced by aspirin and NSAIDs are the most common serious adverse drug reactions reported in the United States, causing an estimated 7,000 deaths each year. Acetaminophen

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[7] Petro, D.J., Ellenberger, C., Treatment of human spasticity with delta-9-tetrahydrocannabinol. *Journal of Clinical Pharmacology* 1981; 21:413-416. (Attached as Exhibit G).

can cause liver damage or kidney failure when used regularly for long periods of time; a recent study suggests it may account for 10% of all cases of end-stage renal disease, a condition that requires dialysis or a kidney transplant.[8] Cannabis, as I pointed out earlier, has never been shown to cause death or serious illness. The University of Iowa conducted a study of cannabis for the relief of pain. Researchers gave oral THC or placebo at random to hospitalized cancer patients who were in severe pain. The THC relieved pain for several hours in doses as low as 5-10 mg, and for even longer at 20 mg. At this dose and in this setting, THC proved to be a sedative as well. It had few physical side effects than other commonly used analgesics.[9]

25. Oncologists are legally permitted to administer the synthetic THC (Marinol) orally in capsule form. But inhaled cannabis may be necessary for several reasons. For one thing, oral THC is subject to the variances of bioavailability. This means that two patients who take the same amount may absorb different proportions of the dose, and a given patient may respond differently on different days, depending on the condition of the intestinal tract and other factors. Furthermore, the effects of smoked cannabis are perceived almost immediately, so patients can smoke

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[8] Perneger, T.V., Whelton, P., Klag, M.J. Risk of kidney failure associated with the use of acetaminophen, aspirin, and nonsteroidal anti-inflammatory drugs. *New England Journal of Medicine*, 1994; 331:25:1675-1679. (Attached as Exhibit H).

[9] R. Noyes, S.F. Brunk, D.A. Baram, and A. Canter, "Analgesic Effect of Delta-9-tetrahydrocannabinol," *Journal of Clinical Pharmacology 15* (February-March 1975): 139-143. (Attached as Exhibit I).

slowly and take only what they need for a therapeutic effect. Patients who swallow Marinol may discover after an hour or so that they have taken too much for comfort or not enough to relieve their symptoms. In any case, a patient who is severely nauseated and constantly vomiting may find it almost impossible to the capsule down. Furthermore, Marinol makes some patients anxious and uncomfortable. Smoked cannabis, unlike Marinol, contains other substances which reduces anxiety caused by the THC.

26. In theory, all the therapeutic properties of cannabis could be used if individual cannabinoids in addition to THC were isolated and made available separately as medicines. But this would be an enormously complicated procedure. Research sponsors would have to determine the therapeutic potential and evaluate the safety of sixty or more substances, synthesize each one found to be useful, and package it as a pill or aerosol. As some of these substances probably act synergistically, it would also be necessary to look at various combination of them. However no drug company would provide the resources deeded for such a project because cannabis can not be patented, it is a plant material containing many chemicals rather than a single one and no drug in the present pharmacopoeia is delivered by smoking.

27. More than 300,000 Americans have died of AIDS. Nearly a million are infected with HIV, and at least a quarter of a million have AIDS. Although the spread of AIDS has slowed among homosexual men, the reservoir is so huge that the number of cases is sure to grow. Women and children as well as both heterosexual and homosexual men are now being affected; the

disease is spreading most rapidly among intravenous drug abusers and their sexual partners. The disease can be attacked with anti-viral drugs, of which the best known are zidovudine (AZT) and protease inhibitors. Unfortunately, these drugs sometimes cause severe nausea that heightens the danger of semi-starvation for patients who are already suffering from nausea and losing weight because of the illness—a condition sometimes called the AIDS wasting syndrome.

28. Cannabis is particularly useful for patients who suffer from AIDS because it not only relieves the nausea but retards weight loss by enhancing appetite. In one study the body weight and caloric intake of twenty-seven marijuana users and ten control subjects were compared for twenty-one days on a hospital research ward. The marijuana smokers ate more than the controls and gained weight; the controls did not. When they stopped smoking marijuana, they immediately started to eat less.[10] When it helps patients regain lost weight, it can prolong life. Although Marinol has been shown to relieve nausea and retard or reverse weight loss in patients with HIV infection, most patients prefer smoked cannabis for the same reasons that cancer chemotherapy patients prefer smoked cannabis. Cannabis is more effective and has fewer unpleasant side effects, and the dosage is easier to adjust. Many patients report that cannabis provides an appetite and pain relief without the semi-comatose effect of narcotics.

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[10] I. Greenberg, J. Kuehnle, J. H. Mendelson, and J.G. Bernstein, "Effects of Marijuana Use of Body Weight and Caloric Intake in Humans," *Journal of Psychopharmacology* (Berlin) 49 (1976): 79-84. (Attached as Exhibit J).

29. Opponents of medical cannabis often object that the evidence of its usefulness, although strong, comes only from case reports and clinical experience. It is true that there are no double-blind controlled studies meeting the standards of the Food and Drug Administration, chiefly because legal, bureaucratic, and financial obstacles have been constantly put in the way. However, we know more about cannabis than about most prescription drugs. Furthermore, individual therapeutic responses are often obscured in group experiments, and case reports and clinical experience are the source of much of our knowledge of drugs. As Dr. Louis Lasagna has pointed out, controlled experiments were not needed to recognize the therapeutic potential of chloral hydrate, barbiturates, aspirin, insulin, or penicillin.[11] Nor was that the way we learned about the use of propranolol for hypertension, diazepam for status epilepticus, and imipramine for enuresis. All these drugs had originally been approved for other purposes.

30. In the experimental method known as the single patient randomized trial, active and placebo treatments are administered randomly in alternation or succession. The method is often used when large-scale controlled studies are inappropriate because the disorder is rare, the patient is atypical, or the response to treatment is idiosyncratic.[12] Several patients have told me that they

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[11] Lasagne, L. Clinical trials in the natural environment. C. Stiechele, W. Abshagan, J. Kich-Weser (eds.). *In Drugs Between Reserach and Regulations*. New York: Springer-Verlag, 1985: 45-49. (Attached as Exhibit K).

[12] Larson, E.B. N-of-1 clinical trials: A technique for improving medical therapeutics. *Western Journal of Medicine* 1990; 152:52-56; Guyatt, G. H. Keller, J.L., Jaeschke, R., et al. The N-of-1

assured themselves of cannabis's effectiveness by carrying out such experiments on themselves, alternating periods of cannabis use with periods of abstention. I am convinced that the medical reputation of cannabis is derived partly from similar experiments conducted by many other patients.

31. Some physicians may regard it as irresponsible to advocate use of a medicine on the basis of case reports, which are sometimes disparaged as merely "anecdotal" evidence which counts apparent successes and ignores apparent failures. That would be a serious problem only if cannabis were a dangerous drug. The years of effort devoted to showing that cannabis is exceedingly dangerous have proved the opposite. It is safer, with fewer serious side effects than most prescription medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics.

32. Based on the best available medical information, it is evident that cannabis should be made available even if only a few patients could get relief from it, because the risks are so small. For example, as I mentioned, many patients with multiple sclerosis find that cannabis reduces their muscle spasma and pain. A physician may not be sure that such a patient will get more relief from cannabis than from the standard drugs baclofen, dantrolene, and diazepam—all of which are potentially dangerous or addictive—but it is almost certain that a serious toxic reaction to cannabis will not

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radomized controlled trial: Clinical usefulness. *Annals of Internal Medicine* 1990; 112:293-299 (Attached as Exhibit L).

occur. Therefore the potential benefit is much greater than any potential risk.

33. During the past few years, the medical uses of cannabis have become increasingly clear to many physicians and patients, and the number of people with direct experience of these uses has been growing. Therefore, the discussion is now turning from whether cannabis is an effective medicine to how it should be made available.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 11th day of September, 1998. at Boston, Massachusetts.

/s/ LESTER GRINSPOON, M.D.
LESTER GRINSPOON, M.D.

INTRODUCED BY COUNCILMEMBER _____

Approved As To Form

[Signature illegible]
City Attorney

ORDINANCE NO. 12076 C.M.S.

AN ORDINANCE OF THE CITY OF OAKLAND ADDING CHAPTER 8.42 TO THE OAKLAND MUNICIPAL CODE PERTAINING TO MEDICAL CANNABIS

The City Council of the City of Oakland does ordain as follows:

Article 1. Chapter 8.42 is hereby added to the Oakland Municipal Code to read as follows:

MEDICAL CANNABIS

Section 1. Findings and Purposes

A. On November 5, 1996, the voters of the State of California adopted by initiative the Compassionate Use Act of 1996, codified at Health and Safety Code Section 11362.5, pertaining to medical use of marijuana. As stated therein, the purposes of the Compassionate Use Act of 1996 are in part to "ensure that seriously ill Californians have the right to obtain and use marijuana

for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief" and to "ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction." The City of Oakland supports the use of medical cannabis in accordance with the Compassionate Use Act of 1996. The purposes of the compassionate Use Act of 1996 are herewith also made purposes of this Chapter.

B. Long before the passage of the Compassionate Use Act of 1996, the City of Oakland was on record as being in support of medical cannabis and in support of Oakland medical cannabis providers, as exemplified by unanimously passed Oakland City Council Resolutions numbered 72379 C.M.S. and 72516 C.M.S.

C. The purpose of this Chapter is to recognize and protect the rights of qualified patients, their caregivers, physicians, and medical cannabis provider associations, and to ensure access to safe and affordable medical cannabis pursuant to the Compassionate Use Act of 1996. In support of this purpose, the City of Oakland recognizes that a medical cannabis provider association, as defined herein, may provide educational information concerning access to safe, affordable, and lawful medical cannabis, and may also distribute safe and affordable medical cannabis in a consistent, reliable, and legal fashion.

D. An additional purpose of this Chapter is to provide immunity to medical cannabis provider associations pursuant to Section 885(d) of Title 21 of the United States Code, which provides that no liability shall be imposed under the federal Controlled Substance Act upon any duly authorized officer of a political subdivision of a state lawfully engaged in the enforcement of any municipal ordinance relating to controlled substances.

Section 2. Definitions

The following words and phrases, whenever used in this Chapter, shall be construed as herein defined.

A. Qualified Patient: "Qualified patient" means a person who obtains a written or oral recommendation or approval from a physician to use cannabis for personal medical purposes.

B. Primary Caregiver: "Primary caregiver" means the person or persons designated by a qualified patient who have consistently assumed responsibility for the housing, health, or safety of that qualified patient.

C. Cannabis: "Cannabis" means marijuana and all parts of the plant Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted

therefrom), fiber, oil, or cake, or the sterilized seeds of the plant that are incapable of germination.

D. Medical Cannabis Provider Association: "Medical cannabis provider association" means a cooperative, affiliation, association, or collective of persons who are qualified patients or primary caregivers, the main purposes of which are to provide education, referral, or network services, and to facilitate or assist in the lawful production, acquisition, and distribution of medical cannabis. An entity may function as a medical cannabis provider association only if designated as such by the City of Oakland pursuant to Section 3 of this Chapter.

E. Officer: "Officer" means designee and shall not have the meaning of that term as used in Section 400 of the Oakland City Charter.

Section 3. Medical Cannabis Distribution Program

The City of Oakland hereby establishes a Medical Cannabis Distribution Program. Such program shall be administered by medical cannabis provider associations. The City Manager shall designate one or more entities as a medical cannabis provider association. Any designated medical cannabis provider association shall enforce the provisions of this Chapter, including enforcing its purpose of insuring that seriously ill Californians have the right to obtain and use marijuana for medical purposes. For the purposes of this Chapter only, a medical cannabis provider association, and its agents, employees and directors while acting within the scope of their duties on behalf of the association, shall be deemed officers of the City of Oakland.

Section 4. No Liability

To the fullest extent permitted by law, the City of Oakland shall assume no liability whatsoever, and expressly does not waive sovereign immunity, with respect to the Medical Cannabis Distribution Program established herein, or for the activities of any medical cannabis provider association. Each medical cannabis provider association designated by the City shall (1) indemnify the City of Oakland; (2) carry insurance in the amounts and of the types that are acceptable to the City's Risk Manager; and (3) name the City as an additional insured.

Section 5. Qualified Patients, Primary Caregivers, and Medical Cannabis Provider Associations

In order to ensure that qualified patients and primary caregivers are not subject to criminal prosecution or sanction, and to ensure that only qualified patients and primary caregivers have access to medical cannabis, the City of Oakland, or medical cannabis provider associations on behalf of the City of Oakland, may issue valid identification cards to qualified patients and primary caregivers upon receipt of a physician's recommendation or approval for medical cannabis.

Section 6. Physician-Patient Confidentiality

Certification processes conducted pursuant to this Chapter shall preserve to the maximum extent possible all legal protections and privileges, consistent with reasonably verifying the qualifications and status of qualified patients and primary caregivers. Disclosure of any patient information to assert facts in support of a

qualified status shall not be deemed a waiver of confidentiality of that information under any provision of law.

Section 7. Transportation of Medical Cannabis

All activities entailing the transportation of medical cannabis, in accordance with this Chapter, shall be lawful when conducted by qualified patients, primary caregivers, or medical cannabis provider associations where the quantity transported and the method, timing, and distance of the transportation are reasonably related to the medical needs of qualified patients.

Section 8. Miscellaneous Applications

Possession and use of the following items shall be lawful when used in accordance with the Compassionate Use Act of 1996 or this Chapter:

A. Pipes, papers, water pipes, vaporizers, and other related paraphernalia:

B. Cannabis products, such as baked goods, tinctures, concentrated cannabis, infusions, oils, salves, and any other cannabis derivatives.

Section 9. Violations and Penalties

A violation of any provision of this Chapter shall be a misdemeanor.

Article 2. Severability

If any provision of this Chapter, or the application thereof to any person or circumstance, is held invalid, that invalidity shall not affect any other provision or application of this Chapter that can be given effect without the invalid provision or application; and to this end, the provisions or applications of this Chapter are severable.

I certify that the foregoing is a full, true and correct copy of an Ordinance passed by the City Council of the City of Oakland, California on

July 28, 1998

CEDA FLOYD
City Clerk and Clerk of the Council

Per [Signature illegible] Deputy

CITY OF OAKLAND [Seal Omitted]

CITY HALL • ONE CITY HALL PLAZA • OAKLAND, CALIFORNIA 9461 [Illegible]

Office of City Manager (510) 238-330 [Illegible]
Robert C. Bobb FAX (510) 238-222 [Illegible]
City Manager TY/TDD (510) 238-372 [Illegible]

August 11, 1998

Mr. Jeff Jones
Executive Director
Oakland Cannabis Buyers' Cooperative
1755 Broadway, Suite 300
Oakland, CA 94612

Dear Mr. Jones:

Pursuant to Chapter 8.42 of the Oakland Municipal Code, the City hereby designates the Oakland Cannabis Buyers Club to administer the City's Medical Cannabis Distribution Program. The designation is subject to the cooperative's agreement to comply with the terms and conditions attached hereto as Exhibit A which hereby are incorporated by reference in this letter as if set forth in full herein.

The designation shall be effective upon the Oakland Cannabis Buyers' Cooperative's acceptance and agreement to the terms and conditions in Exhibit A. Please confirm the Oakland Cannabis Buyers' Cooperative's

agreement to comply with the terms and conditions in Exhibit A by signing below.

Very truly yours,

for [Illegible]
Robert C. Bobb
City Manager

SO AGREED:

JEFF JONES DATE: 8/12/98
JEFF JONES
Executive Director
Oakland Cannabis Buyers' Cooperative

OAKLAND CITY COUNCIL

RESOLUTION NO. 74618 C.M.S.

RESOLUTION DECLARING A LOCAL PUBLIC HEALTH EMERGENCY WITH RESPECT TO SAFE, AFFORDABLE ACCESS TO MEDICAL CANNABIS IN THE CITY OF OAKLAND

WHEREAS, on November 5, 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996, by a YES vote of 55.7 percent, and the residents of Oakland voted YES for Proposition 215 by an overwhelming 79.3 percent; and

WHEREAS, marijuana has been shown to help alleviate pain and discomfort in people suffering from a variety of illnesses including AIDS, cancer, glaucoma, and multiple sclerosis when no other medications have been effective; and

WHEREAS, the City Council of the City of Oakland finds that many of Oakland's residents are suffering from life-threatening or serious illnesses whose painful symptoms are alleviated by the ingestion of cannabis; and

WHEREAS, there is a need to ensure that patients have access to a safe and affordable supply of medical grade marijuana and cannabis products; and

WHEREAS, the City Council finds that the Oakland Cannabis Buyers' Cooperative has provided a well-

organized, safe and responsible opportunity for seriously ill persons to obtain medical cannabis in furtherance of a course of medical treatment; and

WHEREAS, the Oakland City Council passed Resolution 72516 C.M.S. supporting the activities of the Oakland Cannabis Buyers Cooperative and declaring it to be the policy of the City of Oakland that the investigation and arrest of certain individuals involved with the medical use of marijuana shall be a low priority for the City of Oakland; and

WHEREAS, in furtherance of the City's goal of ensuring a safe and affordable supply of medical grade marijuana and cannabis products for seriously ill Oakland residents whose physicians have recommended or approved medical cannabis use in the treatment of their illnesses, the Oakland City Council, pursuant to Ordinance No. 12076, established a City of Oakland marijuana distribution program and designated the Oakland Cannabis Buyers' Cooperative as the City's agent to administer the program; and

WHEREAS, in January 1998, the United States of America filed an action asking the federal district court to enjoin the Oakland Cannabis Buyers' Cooperative and five other entities from providing medical cannabis to seriously ill persons who are authorized by Proposition 215 to use medical cannabis to alleviate their pain and suffering; and

WHEREAS, on May 19, 1998 the federal district court issued a preliminary injunction ordering the Oakland Cannabis Buyers' Cooperative to cease engaging in the manufacture and distribution of marijuana, on the

ground that such activities likely violate federal drug laws; and

WHEREAS, on October 13, 1998 the federal district court authorized the U.S. Marshal to enforce the aforesaid preliminary injunction by entering the cooperative's premises located at 1755 Broadway in Oakland, evicting any and all tenants and padlocking the doors to such premises; and

WHEREAS, on October 19, 1998, the Oakland Cannabis Buyers' Cooperative voluntarily ceased its operations at 1755 Broadway; and

WHEREAS, the Oakland Cannabis Buyers' Cooperative provided medical cannabis to two thousand two hundred (2,200) seriously ill persons, approximately two-thirds of whom are living with AIDS; and

WHEREAS, the closure of the Oakland Cannabis Buyers' Cooperative impairs public safety by encouraging a market for street narcotic peddlers to prey upon Oakland's ill residents by selling them marijuana that may be contaminated and will be of unknown content and potency; and

WHEREAS, the City Council finds that the closure of the Oakland Cannabis Buyers' Cooperative will cause pain and suffering to seriously ill Oakland residents who are unable to cultivate medical strains of cannabis for their personal use and therefore either no longer have access to medical cannabis to alleviate their pain and suffering or purchase contaminated cannabis from street narcotic peddlers;

NOW THEREFORE, be it

RESOLVED: that the City Council of the City of Oakland finds that a public health emergency exists with respect to access to an affordable and safe supply of medical cannabis, and pursuant to Government Code section 8630 does so declare; and be it further

RESOLVED: that the City Council finds that the thousands of seriously ill persons who obtained medical cannabis from the Oakland Cannabis Buyers' Cooperative will endure great pain and suffering and in some cases may die as a result of the closure of the cooperative and other entities that supplied medical cannabis; and be it further

RESOLVED: that the City Council of the City of Oakland urges the federal government to desist from any and all actions that pose obstacles to access to cannabis for Oakland residents whose physicians have determined that their health will benefit from the use of marijuana and recommended or approved medical cannabis use for such residents; and be it further

RESOLVED: that the City Council urges the Alameda County Board of Supervisors to declare a public health emergency with respect to access to medical cannabis; and be it further

RESOLVED: that copies of this resolution shall be forwarded to Senators Boxer and Feinstein, Congresswoman Lee, and the President of the United States, William Jefferson Clinton, urging federal policy-makers to dismiss the current lawsuits against California's

cannabis buyers' clubs and cooperatives; and be it further

RESOLVED: that copies of this resolution shall be forwarded to Governor Pete Wilson, Attorney General Daniel Lungren and all representatives of the City of Oakland in the State Legislature, urging them to comply with the will of the voters as articulated in Proposition 215 by implementing a plan to provide for safe and affordable distribution of marijuana to all patients in medical need of marijuana.

I certify that the foregoing is a full, true and correct copy of a Resolution passed by the City Council of the City of Oakland, California on

Oct 27, 1998

CEDA FLOYD
City Clerk and Clerk of the Council

Per Onetta Middleton Deputy

OAKLAND CITY COUNCIL

RESOLUTION NO. 75713 C.M.S.

INTRODUCED BY COUNCIL MEMBER_____

RESOLUTION RENEWING THE CITY COUNCIL'S DECLARATION OF A LOCAL PUBLIC HEALTH EMERGENCY WITH RESPECT TO SAFE, AFFORDABLE ACCESS TO MEDICAL CANNABIS IN THE CITY OF OAKLAND

WHEREAS, on November 5, 1996, the voters of California passed Proposition 215, the Compassionate Use Act of 1996, by a YES vote of 55.7 percent, and the residents of Oakland voted YES for Proposition 215 by an overwhelming 79.3 percent; and

WHEREAS, marijuana has been shown to help alleviate pain and discomfort in people suffering from a variety of illnesses including AIDS, cancer, glaucoma, and multiple sclerosis when no other medications have been effective; and

WHEREAS, the City Council of the City of Oakland finds that many of Oakland's residents are suffering from life-threatening or serious illnesses whose painful symptoms are alleviated by the ingestion of cannabis; and

WHEREAS, there is a need to ensure that patients have access to a safe and affordable supply of medical grade marijuana and cannabis products; and

WHEREAS, the City Council finds that the Oakland Cannabis Buyers' Cooperative has provided a well-organized, safe and responsible opportunity for seriously ill persons to obtain medical cannabis in furtherance of a course of medical treatment; and

WHEREAS, the Oakland City Council passed Resolution 72516 C.M.S. supporting the activities of the Oakland Cannabis Buyers Cooperative and declaring it to be the policy of the City of Oakland that the investigation and arrest of certain individuals involved with the medical use of marijuana shall be a low priority for the City of Oakland; and

WHEREAS, in furtherance of the City's goal of ensuring a safe and affordable supply of medical grade marijuana and cannabis products for seriously ill Oakland residents whose physicians have recommended or approved medical cannabis use in the treatment of their illnesses, the Oakland City Council, pursuant to Ordinance No. 12076, established a City of Oakland marijuana distribution program and designated the Oakland Cannabis Buyers' Cooperative as the City's agent to administer the program; and

WHEREAS, in January 1998, the United States of America filed an action asking the federal district court to enjoin the Oakland Cannabis Buyers' Cooperative and five other entities from providing medical cannabis to seriously ill persons who are authorized by Proposition 215 to use medical cannabis to alleviate their pain and suffering; and

WHEREAS, on May 19, 1998 the federal district court issued a preliminary injunction ordering the Oakland Cannabis Buyers' Cooperative to cease engaging in the manufacture and distribution of marijuana, on the ground that such activities likely violate federal drug laws; and

WHEREAS, on October 13, 1998 the federal district court authorized the U.S. Marshal to enforce the aforesaid preliminary injunction by entering the cooperative's premises located at 1755 Broadway in Oakland, evicting any and all tenants and padlocking the doors to such premises; and

WHEREAS, on October 19, 1998, the Oakland Cannabis Buyers' Cooperative voluntarily ceased its operations at 1755 Broadway; and

WHEREAS, the Oakland Cannabis Buyers' Cooperative provided medical cannabis to two thousand two hundred (2,200) seriously ill persons, approximately two-thirds of whom are living with AIDS; and

WHEREAS, the closure of the Oakland Cannabis Buyers' Cooperative impairs public safety by encouraging a market for street narcotic peddlers to prey upon Oakland's ill residents by selling them marijuana that may be contaminated and will be of unknown content and potency; and

WHEREAS, the City Council finds that the closure of the Oakland Cannabis Buyers' Cooperative will cause pain and suffering to seriously ill Oakland residents who are unable to cultivate medical strains of cannabis for their personal use and therefore either no longer

have access to medical cannabis to alleviate their pain and suffering or purchase contaminated cannabis from street narcotic peddlers; and

WHEREAS, on October 27, 1998, the City Council passed Resolution No. 74618 C.M.S. declaring a local public health emergency with respect to safe, affordable access to medical cannabis in the City of Oakland;

NOW THEREFORE, be it

RESOLVED: that the City Council of the City of Oakland finds that a public health emergency exists with respect to access to an affordable and safe supply of medical cannabis, and pursuant to Government Code section 8630 does so declare; and be it further

RESOLVED: that the City Council finds that the thousands of seriously ill persons who obtained medical cannabis from the Oakland Cannabis Buyers' Cooperative will endure great pain and suffering and in some cases may die as a result of the closure of the cooperative and other entities that supplied medical cannabis; and be it further

RESOLVED: that the City Council of the City of Oakland urges the federal government to desist from any and all actions that pose obstacles to access to cannabis for Oakland residents whose physicians have determined that their health will benefit from the use of marijuana and recommended or approved medical cannabis use for such residents; and be it further

RESOLVED: that the City Council urges the Alameda County Board of Supervisors to declare a public health

emergency with respect to access to medical cannabis; and be it further

RESOLVED: that copies of this resolution shall be forwarded to Senators Boxer and Feinstein, Congresswoman Lee, and the President of the United States, William Jefferson Clinton, urging federal policy-makers to dismiss the current lawsuits against California's cannabis buyers' clubs and cooperatives; and be it further

RESOLVED: that copies of this resolution shall be forwarded to Governor Gray Davis, Attorney General Lockyer and all representatives of the City of Oakland in the State Legislature, urging them to comply with the will of the voters as articulated in Proposition 215 by implementing a plan to provide for safe and affordable distribution of marijuana to all patients in medical need of marijuana.

In Council, Oakland, California, May 16, 2000, 1999

PASSED BY THE FOLLOWING VOTE:

AYES- Brunner, Chang, Miley, Nadel, Reid, Russo, Spees, and President De La Fuente - 8

NOES- None

ABSENT- None

ABSTENTION- None

Attest CEDA FLOYD
CEDA FLOYD
City Clerk And Clerk Of The Council Of The
City Of Oakland, California

California Marijuana Arrests, 1930-1999

Source: Cal. Dept. of Justice, Criminal Justice Statistics Center
"Adult and Juvenile Arrests Reported," various years

Year	Misdemeanors	Felonies	Total
1930		228	228
1931		91	91
1935		140	140
1960		5,155	5,155
1961		3,794	3,794
1962		3,743	3,743
1963		5,518	5,518
1964		7,560	7,560
1965		10,002	10,002
1966		18,243	18,243
1967		37,514	37,514
1968		47,939	47,939
1969		51,414	51,414
1970		64,880	64,880
1971		61,199	61,199
1972	3,500	73,061	76,561
1973	3,500	88,110	91,610
1974	3,500	99,597	103,097
1975	3,500	85,757	89,257
1976	34,110	19,284	53,394
1977	34,110	17,262	51,372
1978	35,424	17,397	52,821
1979	32,796	19,263	52,059
1980	38,270	20,509	58,779
1981	43,791	20,771	64,562
1982	42,904	20,737	63,641
1983	43,803	19,926	63,729

1984	42,219	21,350	63,569
1985	43,181	24,182	67,363
1986	30,105	19,938	50,043
1987	32,424	18,722	51,146
1988	27,373	16,853	44,226
1989	25,825	16,325	42,150
1990	20,834	16,819	37,653
1991	19,383	14,050	33,433
1992	22,493	14,980	37,473
1993	25,914	14,357	40,271
1994	31,294	14,668	45,962
1995	35,854	14,449	50,303
1996	41,595	15,361	56,956
1997	43,169	14,498	57,667
1998	46,600	14,344	60,944
1999	48,673	14,171	62,844

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No. 00-151

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONER

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51 pp

QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, forecloses a "medical necessity" defense to the Act's prohibition against manufacturing and distributing marijuana, a schedule I controlled substance.

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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-11a)[1] is reported at 190 F.3d 1109. The May 13, 1998 memorandum and order of the district court is reported at 5 F. Supp. 2d 1086 (App. 41a-81a). The other opinions and orders of the district are unreported (App. 12a-40a).

JURISDICTION

The judgment of the court of appeals was entered on September 13, 1999. A petition for rehearing was denied on February 29, 2000 (App. 82a). On May 22,

[1] "App." refers to the separately bound appendix to the petition for a writ of certiorari.

2000, Justice O'Connor extended the time within which to file a petition for a writ of certiorari to and including June 28, 2000. On June 19, 2000, Justice O'Connor further extended the time within which to file a petition to and including July 28, 2000, and the petition was filed on that date. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761, are set forth at App. 83a-92a.

STATEMENT

1. a. The Controlled Substances Act (CSA) makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1); see *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975).[2] The CSA imposes criminal and civil penalties for violations of the Act, see 21 U.S.C. 841-863, and further gives district courts jurisdiction to enjoin violations of the Act. 21 U.S.C. 882(a).

The CSA classifies controlled substances according to their inclusion in one of five schedules.[3] The listing of a substance in one of the five schedules depends on the extent (if any) to which the particular drug has a cur-

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[2] The CSA similarly makes it a crime to possess any controlled substance except as otherwise authorized by the Act. 21 U.S.C. 844(a).

[3] The Act defines a "controlled substance" as "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V" of the Act. 21 U.S.C. 802(6).

rently accepted medical use, the level of its potential for abuse, and the degree of psychological or physical dependence to which its use may lead. 21 U.S.C. 812(b). The Act then imposes restrictions on the manufacture and distribution of the substance according to the schedule in which it has been placed. See 21 U.S.C. 821-829.

A drug is included in schedule I, the most restrictive schedule, if it "has a high potential for abuse," "has no currently accepted medical use in treatment in the United States," and has "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). A drug is included in schedule II if it "has a high potential for abuse," but "has a currently accepted medical use in treatment in the United States" or "a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2)(A) and (B). Schedules III through V consist of drugs that similarly have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(3)(B), (4)(B) and (5)(B), but have a lower potential for abuse and a more limited degree of dependence than drugs listed in the preceding schedule. 21 U.S.C. 812(b)(3)-(5).

When it enacted the CSA in 1970, Congress specified certain substances to be included in each of the schedules as an initial matter. Pub. L. No. 91-513, Tit. II, § 202, 84 Stat. 1248-1252; see 21 U.S.C. 812(a). Congress classified marijuana and tetrahydrocannabinols as schedule I controlled substances from the outset, see 84 Stat. 1249 (schedule I(c)(10) and (17)), and they have remained schedule I substances ever since 1970. See 21 U.S.C. 812(c) (schedule I(c)(10) and (17)).[4]

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[4] "Marijuana (*cannabis sativa L.*) is a psychoactive drug made of the leaves, flowers, and stems of the Indian Hemp plant. It

The Attorney General may add other substances to the schedules if she finds, pursuant to procedures specified in the Act, that the drugs meet the statutory criteria. See 21 U.S.C. 811; *Touby* v. *United States*, 500 U.S. 160 (1991).

The CSA establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970); see also *Moore*, 423 U.S. at 141 (The CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal.") (quoting H.R. Rep. No. 1444, *supra*, Pt. 1, at 3). No individual or entity may distribute or dispense a schedule I controlled substance except as part of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100(b); see also 21 U.S.C. 355(i) (discussed at p. 6, note 5, *infra*). By contrast, drugs listed in schedules II through V may be dispensed and prescribed for medical use. Physicians, pharmacies, and other legitimate handlers of drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that mandate registration with the DEA, establish security controls, impose recordkeeping

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derives its psychoactive properties from delta-9-tetrahydrocannabinol (THC), which exists in varying concentrations in the plant, depending on its origin, growing conditions, and cultivation." *National Org. for the Reform of Marijuana Laws* v. *Bell*, 488 F. Supp. 123, 128 (D.D.C. 1980) (three-judge court). In addition to THC, marijuana contains over 400 separately identified chemicals. 57 Fed. Reg. 10,499, 10,500, 10,507 (1992). See also 21 U.S.C. 802(16) (defining marijuana to mean "all parts of the plant Cannabis sativa L").

and reporting obligations, and permit the drug to be distributed and dispensed only pursuant to specified order-form and prescription requirements. See 21 U.S.C. 821-829; 21 C.F.R. 1301-1306.

The CSA also establishes an exclusive set of statutory procedures under which controlled substances that have been placed in schedule I (or any other schedule) may be transferred to another schedule or be entirely removed from the schedules. 21 U.S.C. 811(a). Pursuant to that process, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana to a less restrictive schedule may petition the Attorney General to initiate a rulemaking proceeding to reschedule marijuana. 21 U.S.C. 811(a). Before initiating such proceedings, the Administrator of DEA, to whom the Attorney General has delegated her authority under the CSA (see 28 C.F.R. 0.100(b)), must request from the Secretary of Health and Human Services (HHS) a scientific and medical evaluation and a recommendation as to whether the substance should be reclassified or decontrolled. The recommendations of the Secretary are binding on the Administrator with respect to scientific and medical matters. 21 U.S.C. 811(b). If the Administrator concludes that there is substantial evidence that the substance should be rescheduled or decontrolled, he shall institute a public rulemaking proceeding on the record. 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in the courts of appeals. 21 U.S.C. 877; see, *e.g.*, *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994) (upholding Administrator's decision declining to transfer marijuana from schedule I to schedule II).

b. In addition to the restrictions under the CSA, marijuana is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* Under the FDCA, "new" drug includes any drug that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 321(p); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-632 (1973); *United States* v. *Rutherford*, 442 U.S. 544, 546-548, 549-550 n.7 (1979). The FDCA prohibits the "introduc[tion] or deliver[y] for introduction into interstate commerce" of a new drug, absent the submission of a new drug application (NDA) and a finding by the FDA that the drug is both safe and effective for each of its intended uses. 21 U.S.C. 355(a) and (b); *Rutherford*, 442 U.S. at 546.[5] The drug must be proven safe through "adequate tests by all methods reasonably applicable," and it must be proven effective by "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. 355(d).

c. In a statutory provision enacted in 1998 and entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared that:

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[5] The FDCA authorizes the Secretary to promulgate regulations for exempting from the new drug restrictions "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. 355(i).

(1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;

* * * * *

(3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana * * *;

(4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 355], before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;

(5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;

(6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

* * * * *

(11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circum-

> vent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration.

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761.

2. On January 9, 1998, the United States brought this suit in the United States District Court for the Northern District of California seeking an injunction against six marijuana distributors, popularly known as "cannabis clubs," and ten associated individuals, alleging that the defendants' ongoing distribution (and in some cases manufacture) of marijuana violated the CSA. Many such groups formed in the wake of California's Compassionate Use Act of 1996, or Proposition 215, which purports to authorize under state law the possession and cultivation of marijuana for medical purposes upon a physician's recommendation. See Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West 1999).[6]

On May 19, 1998, the district court issued a preliminary injunction under 21 U.S.C. 882(a) that enjoined respondents Oakland Cannabis Buyers' Cooperative (OCBC) and its director and other marijuana distributors from "engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute mari-

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[6] Proposition 215, however, neither authorizes the distribution of marijuana for medical purposes nor exempts such conduct from prosecution under California's laws that criminalize the distribution of marijuana. *People* v. *Peron*, 70 Cal. Rptr. 2d 20, 25-29 (1997), review denied, No. A077630 (Feb. 25, 1998). Proposition 215 also does not purport to displace any federal law applicable to marijuana.

juana, in violation of 21 U.S.C. § 841(a)(1)." App. 39a-40a (order); *id.* at 41a-81a (memorandum opinion). The court found it "undisputed that [respondents] distribute marijuana * * * to seriously ill patients or their primary caregivers for personal use by the patient upon a physician's recommendation." *Id.* at 63a. The court also rejected a variety of legal contentions offered by respondents to exempt themselves from the CSA's prohibition against the manufacture and distribution of marijuana, including arguments based on a "medical necessity" theory. *Id.* at 68a-71a. The court noted that the "medical necessity" defense "has never been allowed to exempt a defendant from the criminal laws on a blanket basis." *Id.* at 70a.

Respondents did not appeal the injunction but rather violated it by openly distributing marijuana to numerous persons. App. 21a-23a. On October 13, 1998, the district court issued an order finding respondents in civil contempt. *Id.* at 20a-38a. On October 16, 1998, the district court issued an order denying respondents' motion to modify or dissolve the injunction to include a broad exemption for distribution to persons claiming a "medical necessity" to smoke marijuana. Respondents' motion had requested a ruling permitting them to distribute marijuana to persons who obtained a physician's certificate stating that they need marijuana to alleviate or treat a serious medical condition. See *id.* at 18a-19a (denying motion for modification); *id.* at 7a-8a, 28a-29a (describing proposed "medical necessity" defense).

3. In a per curiam opinion, the court of appeals reversed the district court's denial of the motion to modify the injunction based on a physician's statement of "medical necessity." App. 1a-11a. The court of appeals held that the district court, in construing its equitable power to issue an injunction, erred in not

"tak[ing] into account a legally cognizable defense that likely would pertain in the circumstances." *Id.* at 8a. The court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." *Id.* at 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)).

The court of appeals further concluded that, in deciding whether to issue or modify the injunction, the district court abused its discretion in not considering what the court of appeals described as "a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses." App. 9a-10a. "Indeed," the court observed, "the City of Oakland has declared a public health emergency" in response to the district court's denial of respondents' motion to modify the injunction to authorize respondents to distribute marijuana. *Id.* at 10a. The court also expressed the view that "[t]he evidence in the record is sufficient to justify the requested modification," and the court had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Ibid.* "[B]y contrast," the court continued, the government had identified no "interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes." *Id.* at 11a. The court of appeals therefore remanded the matter to the district court "to reconsider" respondents' request for a modification of the injunction to

exempt persons who have a medical need for marijuana. *Ibid.*

4. Following the Ninth Circuit's decision, on May 30, 2000, OCBC filed a motion with the district court to modify the district court's injunction entered on May 19, 1998. On July 17, 2000, the district court granted OCBC's motion. App. 12a-17a. The court explained:

> On remand the government has still not offered any evidence to rebut [OCBC's] evidence that cannabis is medically necessary for a group of seriously ill individuals. Instead, the government continues to press arguments which the Ninth Circuit rejected, including the argument that the Court must find that enjoining the distribution of cannabis to seriously ill individuals is in the public interest because Congress has prohibited such conduct in favor of the administrative process regulating the approval and distribution of drugs.

Id. at 13a. The court therefore stated that, "[a]s a result of the government's failure to offer any new evidence in opposition to [OCBC's] motion, and in light of the Ninth Circuit's opinion, the Court must conclude that modifying the injunction as requested is in the public interest and exercise its equitable discretion to do so." *Ibid.*

The district court accordingly issued an Amended Preliminary Injunction Order which reaffirmed that respondents are preliminary enjoined from manufacturing or distributing marijuana, or possessing marijuana with the intent to manufacture or distribute it, in violation of 21 U.S.C. 841(a)(1). App. 15a-16a. The district court further ordered, however, that

> [t]he foregoing injunction does not apply to the distribution of cannabis by [respondents] to patient-

> members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or alleviating the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

Id. at 16a-17a.[7]

SUMMARY OF ARGUMENT

A. 1. A common law defense of "necessity" permits a court or jury to acquit a defendant of a criminal offense based upon a finding that the defendant acted to prevent an evil that is greater than that sought to be avoided by the legislature in criminalizing the conduct at issue. *United States* v. *Bailey*, 444 U.S. 394, 410 (1980). The defense is not available, however, if the statute defining the criminal offense reflects a legis-

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[7] On August 29, 2000, this Court entered an order granting the government's application for a stay of the district court's July 17, 2000, orders, pending appeal of the order to the court of appeals. 121 S. Ct. 21. On December 12, 2000, the court of appeals postponed oral argument on that appeal pending this Court's decision on writ of certiorari here.

lative resolution of the conflicting values at stake or other judgment that precludes the defense. Wayne R. LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 627-629 (2d ed. 1986); Model Penal Code § 3.02(1)(a) (1962).

2. The text, structure and purposes of the Controlled Substances Act (CSA) establish a judgment by Congress that necessarily precludes a "necessity" defense to a charged violation of the Act based on an asserted medical need to smoke marijuana. By classifying marijuana as a schedule I controlled substance, Congress, in the text of the CSA itself, has declared that marijuana has no "currently accepted medical use in treatment in the United States" and has no "accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(B) and (C). Congress thus has banned the distribution of marijuana for *any* purpose, including purported medical use—"[e]xcept as authorized" by the Act itself (21 U.S.C. 841(a)(1)), *i.e.*, unless the person dispensing the drug is a practitioner registered with the Drug Enforcement Administration to conduct research that has been specifically approved by the Food and Drug Administration (21 U.S.C. 355(i) and 823(f)). The CSA thus leaves no doubt that Congress has considered the possibility of the medical use of marijuana and has specifically rejected it.

3. A "medical necessity" defense also cannot be reconciled with the provisions of the CSA that substantially restrict and control the distribution and use of all controlled substances, even those that are listed in schedules II through V and that therefore have been determined to have an accepted medical use. The CSA requires legitimate handlers of all controlled substances to register with the DEA and follow recordkeeping and reporting obligations, and the Act further requires

manufacturers and distributors to use specified order forms when distributing schedule I or II controlled substances, and requires practitioners who dispense drugs to follow specified prescription requirements. 21 U.S.C. 821-829. The Ninth Circuit's decision countenances the ongoing distribution of marijuana without any of those stringent controls, and thus defeats the CSA's purposes to protect the public from the dangers associated with the abuse of illicit drugs and their diversion from legitimate channels.

4. The asserted defense of "medical necessity" likewise is fundamentally inconsistent with the CSA's provisions that govern the reclassification of controlled substances or their removal from scheduling altogether. Congress in the CSA assigned to the Attorney General, in consultation with the Secretary of HHS, the responsibility to decide whether to reclassify or remove marijuana from schedule I, if she determines that the existing scientific and medical data support the conclusion that marijuana no longer meets the statutory criteria of a schedule I drug. 21 U.S.C. 811(a)-(c). Congress also provided that any final decision by the Attorney General to retain or change the inclusion of marijuana in schedule I would be subject to review by a court of appeals, which must give conclusive effect to the Attorney General's factual findings that are supported by substantial evidence. 21 U.S.C. 877. Those provisions manifest a congressional intent to prevent organizations such as respondents from circumventing and subverting those procedures by attempting to persuade a district court or jury on a case-by-case basis whether the illegal distribution of marijuana is justified because of an asserted medical use for the drug.

5. Finally, a "medical necessity" defense cannot be reconciled with the 1998 statute that Congress passed

in specific response to attempts by States to legalize marijuana use for medical purposes. That statute unambiguously expresses Congress's continued adherence to the position that "marijuana * * * has not been proven safe and effective for medical purposes" and Congress's insistence that marijuana may not be used for asserted medical purposes "without * * * the approval of the Food and Drug Administration" under the FDCA. 112 Stat. 2681-760 to 2681-761.

B. A district court lacks the equitable discretion to craft an injunction that permits the distribution of marijuana for medical use in violation of the Act based on the court's own view that such conduct furthers the public interest. A court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937); accord *TVA* v. *Hill*, 437 U.S. 153, 194 (1978). This Court adhered to that rule in *United States* v. *Rutherford*, 442 U.S. 544 (1979), in holding that a district court lacked the power to enter an injunction that permitted the use of an unapproved drug, Laetrile, by terminally ill cancer patients. The Court reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that a court therefore may not override Congress's policy choice that the drug not be distributed absent a finding by the FDA under the FDCA that the drug is safe and effective. *Id.* at 551.

The CSA likewise "makes no special provision" for marijuana use to treat patients who claim that marijuana is the only drug that will treat or alleviate their medical conditions. Congress already has determined that the illegal use and distribution of marijuana have "a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C.

801(2), and that marijuana has no "currently accepted medical use in treatment in the United States"; has no "accepted safety for use * * * under medical supervision"; and is "unsafe, even under medical supervision." 21 U.S.C. 812(b)(1)(B) and (C); 112 Stat. 2681-760 to 2681-761. Congress therefore categorically has banned the unauthorized distribution of marijuana for all purposes, including purported medical uses, outside the strict controls established by the Act. 21 U.S.C. 841(a)(1). A district court may not override those determinations by reweighing the scientific and medical data and social policies considered by Congress, the Attorney General, and the Secretary of Health and Human Services, and concluding that the public interest supports the illegal distribution of marijuana.

ARGUMENT

THE CONTROLLED SUBSTANCES ACT FORECLOSES A "MEDICAL NECESSITY" DEFENSE IN BOTH CRIMINAL AND CIVIL PROCEEDINGS UNDER THE ACT

This case presents the question whether a defendant who violates the prohibitions in the Controlled Substances Act (CSA) on the distribution of marijuana, a schedule I controlled substance, nonetheless may avoid liability under the Act based on a claim that the use of marijuana by the person to whom it is distributed is medically necessary. In recognizing the availability of a common law defense of "medical necessity" under the CSA, the court of appeals has sanctioned the ongoing distribution of marijuana for asserted medical purposes when such conduct otherwise would admittedly violate the Act. Indeed, the decision goes further and relegates to individual district courts and juries the power

to determine in individual cases brought by the government under the CSA whether and the manner in which marijuana can be distributed for an asserted medical use. As we explain below, however, Congress in the CSA has foreclosed a "medical necessity" defense, whether asserted in a criminal prosecution under 21 U.S.C. 841(a)(1) or in a civil enforcement proceeding under 21 U.S.C. 882(a).

A. The CSA's Text, Structure, And Policies Bar A "Medical Necessity" Defense To A Charged Criminal Violation Of The Act

1. The common law defense of "necessity" is often referred to as a "choice of evils" defense. The defense permits a court or jury to excuse a defendant's criminal conduct if the defendant reasonably believes that the conduct was necessary to avert an evil or harm that is more serious than that sought to be prevented by the law defining the criminal offense charged. See *United States* v. *Bailey*, 444 U.S. 394, 410 (1980); Wayne R. LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 627-629 (2d ed. 1986) (LaFave); Model Penal Code § 3.02(1)(a) (1962).

A necessity defense has no application, however, in the face of a contrary legislative judgment that the criminal action is not justified by a claimed necessity to commit the prohibited act. "The defense of necessity is available only in situations wherein the legislature has not itself, in its criminal statute, made a determination of values. If it has done so, its decision governs." LaFave 629 (footnote omitted).[8] Thus, "a legislative

[8] Stated differently, criminal conduct may be excused based on necessity only "when a real legislature would formally do the same under those circumstances." *United States* v. *Schoon*, 971 F.2d 193, 196-197 (9th Cir. 1991), cert. denied, 504 U.S. 990 (1992).

purpose to exclude the justification claimed [must] not otherwise plainly appear." Model Penal Code § 3.02(1)(c); see also *id.* (explanatory note) ("The legislature must not have previously foreclosed the choice that was made by resolving the conflict of values at stake."); *United States* v. *Kabat*, 797 F.2d 580, 591-592 (8th Cir. 1986) ("The necessity defense was never intended to excuse criminal activity by those who disagree with the decisions and policies of the lawmaking branches of government: in such cases the 'greater harm' sought to be prevented would be the course of action chosen by elected representatives."), cert. denied, 481 U.S. 1030 (1987). Accordingly, the defense "cannot succeed" if "the legislature ha[s] itself canvassed the issue and determined what the choice should be," because "[t]he legislature, so long as it acts within constitutional limits, is always free to make such a choice and have its choice prevail." Model Penal Code § 3.02(1) (cmt. 2) (footnote omitted).[9]

This Court applied those principles in *United States* v. *Bailey*, *supra*, in considering whether prisoners could

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[9] The Supreme Court of New Jersey similarly has defined the limits of the necessity defense:

> In essence [the necessity defense] reflects a determination that if, in defining the offense, the legislature had foreseen the circumstances faced by the defendant, it would have created an exception. It would have balanced the competing values and chosen the lesser evil. Obviously, then, the defense is available at common law only when the legislature has not foreseen the circumstances encountered by a defendant. If it has in fact anticipated the choice of evils and determined the balance to be struck between the competing values, defendants and courts alike are precluded from reassessing those values to determine whether certain conduct is justified.

State v. *Tate*, 505 A.2d 941, 946 (1986).

avoid criminal liability under 18 U.S.C. 751(a), which prohibits escape from the custody of the Attorney General, based on a defense that the escape was necessary to avoid unsafe prison conditions. The Court held that such a defense was unavailable in that case because the prisoners had failed to surrender or return to custody as soon as the claimed conditions had lost their coercive force. 444 U.S. at 410-415. The Court reasoned that the recognition of a necessity defense in those circumstances would conflict with Section 751(a)'s purpose to guard against the continuing threat to society posed by an escaped prisoner. *Id.* at 412-413. The Court further explained that, although the common law defense "may well have been contemplated by Congress when it enacted [Section] 751(a), * * * some duty to return * * * must be an essential element of the defense unless the congressional judgment that escape from prison is a crime be rendered wholly nugatory." *Id.* at 416 n.11.

2. a. The CSA's provisions leave no doubt that respondents in this case may not invoke a supposed "medical necessity" for individuals to smoke marijuana in certain circumstances to justify the ongoing distribution of marijuana in flagrant violation of the express terms of the CSA. Congress in the CSA has declared that "[t]he illegal * * * distribution[] and * * * improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). The CSA therefore makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by" the Act itself. 21 U.S.C. 841(a)(1); see *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975).

Since the enactment of the CSA in 1970, marijuana has been classified as a schedule I controlled substance, a classification which means that marijuana has been found to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). In the 1998 legislation entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress reiterated those findings, and reaffirmed its view that schedule I drugs are "unsafe, even under medical supervision," and that the CSA makes it "illegal to manufacture, distribute, or dispense marijuana." Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760. Moreover, as a schedule I controlled substance, the CSA unequivocally provides that marijuana may not be dispensed to any individual outside of a strictly controlled research project that has been registered with the DEA and approved by the FDA. 21 U.S.C. 355(i), 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100(b).

Congress thus expressly has considered the possibility of the use of marijuana for medical purposes and has specifically rejected it. In those circumstances, to permit respondents to distribute marijuana for medical use would render Congress's judgment to criminalize the unauthorized distribution of marijuana "wholly nugatory." *Bailey*, 444 U.S. at 416 n.11. It is therefore inconceivable that Congress would have endorsed the illegal distribution of marijuana for medical purposes whenever such conduct was necessary to avert medical harm.

b. The recognition of a "medical necessity" defense also cannot be reconciled with the stringent controls that Congress placed on *all* controlled substances, 21 U.S.C. 821-829, even those drugs listed in schedules II

through V that *have* "a currently accepted *medical use* in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B) (emphasis added). The House Report explains that the CSA "provides for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 3 (1970); see also *Moore*, 423 U.S. at 141. The House Report further explains that Congress expected that the CSA would "significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6; see also *Moore*, 423 U.S. at 135 (describing the CSA's purpose to guard against the "diversion of drugs from legitimate channels to illegitimate channels").

To those ends, the CSA requires manufacturers, distributors, and dispensers of all controlled substances to register with the DEA. 21 U.S.C. 821, 822(a), 823; 21 C.F.R. 1301. The Act also requires registrants to adopt effective controls to guard against the theft or diversion of controlled substances, 21 U.S.C. 823; 21 C.F.R. 1301.71-1301.76, and authorizes the Attorney General to inspect a registrant's establishment, 21 U.S.C. 822(f), 880. The Act imposes other significant restrictions on the distribution of controlled substances to ensure a closed system of distribution. The Act requires the Attorney General to determine production quotas for schedules I and II controlled substances, 21 U.S.C. 826; 21 C.F.R. 1303; imposes substantial recordkeeping and reporting requirements on registrants, 21 U.S.C. 827;

21 C.F.R. 1304; disallows the distribution of schedule I and II drugs except pursuant to an order form issued by the DEA, 21 U.S.C. 828(a); 21 C.F.R. 1305; and establishes prescription requirements for the dispensing of drugs in schedules II through V, 21 U.S.C. 829; 21 C.F.R. 1306.[10]

The Ninth Circuit's decision completely abandons even any pretense of requiring respondents to comply with those provisions. Instead, it essentially permits respondents to function as an unregulated and unsupervised marijuana pharmacy—one that may distribute an unlimited amount of marijuana to an unlimited number of persons, as long as those persons assert, to the satisfaction of respondents (and later a judge or jury), that marijuana is the most effective drug for a serious medical condition. App. 7a-8a, 9a-10a. The recognition of a "medical necessity" defense not only flouts the CSA's "'closed' system of drug distribution," it also utterly defeats the CSA's purposes to establish a comprehensive and unified approach to "dangerous drug control" and to guard against the risks of drug abuse and the diversion of controlled substances from "legitimate channels into the illicit market." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6.[11] The fact that the Ninth

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[10] The Attorney General also may deny, revoke, or suspend a registration under circumstances specified in the Act. 21 U.S.C. 823, 824; 21 C.F.R. 1301.31-1301.37.

[11] Although the City of Oakland has passed a resolution that purports to establish a "Medical Cannabis Distribution Program" and designates OCBC as the City's agent to administer the program (J.A. 145, 148), respondents do not assert that the City's program comes close to complying with any of the strict controls imposed by the CSA to protect against marijuana abuse or diversion of the drug. Indeed, on several occasions, OCBC dispensed marijuana from its "Budbar" to undercover DEA agents who

Circuit's decision has countenanced respondents' distribution of marijuana, a schedule I drug, without *any* of the stringent controls placed on less restricted drugs listed in schedules II through V, simply highlights the absurdity of suggesting that a "medical necessity" defense can be reconciled with the CSA.

c. The recognition of a "medical necessity" defense under the CSA similarly conflicts with Congress's determination that the controls placed on schedule I controlled substances may not be altered unless and until the Attorney General and the Secretary of HHS follow the statutory procedures specified in the Act for the rescheduling of drugs. The CSA provides that any interested person may petition the DEA to initiate a rulemaking proceeding if he or she believes that medical, scientific, or other relevant data warrant transferring marijuana from schedule I to a less restrictive

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presented a membership card that OCBC had issued to another DEA agent based on a-phony physician statement. See J.A. 47-50, 53-61, 62-66. OCBC also apparently relies on patient-purchasers to determine what type of marijuana is medically appropriate. J.A. 50 ("[T]he OCBC currently had seven kinds of marijuana for sale, all displayed. * * * I then purchased * * * marijuana with 'brand name' of 'Northern Lights.'"); J.A. 60 ("The sales counter * * * contained several small bottles marked 'Small Hash Oil—$30,' and 'Large Hash Oil—$60.' I also observed a small black square substance that was labeled 'Afghani Hash, 20 grams—$400. * * * I asked for one-eighth ounce of the 'House Special.'"); J.A. 65 (When the OCBC clerk "asked me what I wanted to purchase. I pointed to a clear plastic baggie labeled 'Mexican AA-Grade A.'"); J.A. 72 ("I * * * asked to purchase * * * marijuana with the 'brand name' of 'That's Purdy.'"). Moreover, DEA agents visiting OCBC repeatedly detected the smell of burnt marijuana and observed marijuana either being smoked or grown on the premises. J.A. 49-50, 54, 57; see also J.A. 58 (An OCBC clerk "handed me several bags [of marijuana], and informed me that, 'it's really good, I've just smoked some myself.'").

schedule, so as to allow its use for medical purposes under the Act. 21 U.S.C. 811.[12] Moreover, the CSA provides that any final administrative decision declining to reschedule marijuana is subject to review by the courts of appeals, which must uphold the Attorney General's factual findings if supported by substantial evidence. 21 U.S.C. 877. Based on that statutory framework, the courts of appeals uniformly have held that the statutory rescheduling process is the exclusive means by which criminal defendants charged with violating the Act may challenge marijuana's placement in schedule I. See, *e.g.*, *United States* v. *Burton*, 894 F.2d 188, 192 (6th Cir.) ("it has repeatedly been determined, and correctly so, that reclassification is clearly a task for the legislature and the attorney general and not a judicial one"), cert. denied, 498 U.S. 857 (1990).[13]

Here, respondents do not claim that they have petitioned the Attorney General to reschedule or decontrol marijuana on the ground that the drug has a currently accepted medical use. Cf. *Bailey*, 444 U.S. at 410 (A necessity defense is unavailable "if there was a reasonable, legal alternative to violating the law.").

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[12] We have been informed by the DEA that in December 1997, the DEA referred to the Secretary of HHS a petition by John Gettman to reschedule marijuana because of an asserted lack of a high potential for abuse. HHS has informed us that its evaluation is in the final stages. After completion, the recommendation will be transmitted to the Administrator of the DEA.

[13] Accord *United States* v. *Greene*, 892 F.2d 453, 455 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); *United States* v. *Wables*, 731 F.2d 440, 450 (7th Cir. 1984); *United States* v. *Fogarty*, 692 F.2d 542, 547 n.4 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); *United States* v. *Middleton*, 690 F.2d 820, 823 (11th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Kiffer*, 477 F.2d 349, 357 (2d Cir.), cert. denied, 414 U.S. 831 (1973).

Rather, respondents contend that Congress has consented to a common law scheme in which respondents in the first instance may decide whether smoking marijuana is medically appropriate. That contention simply flies in the face of Congress's contrary judgment that it is the exclusive province of the Attorney General and the Secretary of HHS, under the statutory and administrative procedures set forth in the CSA, to determine, on a uniform and nationwide basis, whether the state of scientific and medical evidence warrants the use of marijuana for medical purposes—and if so, for which purposes and under what circumstances and restrictions. Congress most assuredly did not relegate that determination to respondents, or to individual courts and juries whenever a defendant asserts a "medical necessity" defense to a charged violation of the Act.[14]

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[14] Respondents argue (Br. in Opp. 24) that this Court should be "particularly reluctant to assume" that Congress has foreclosed a "medical necessity" defense because individuals have a constitutional right to make "personal health decisions." Even if we assume, arguendo, that respondents, who are distributors of marijuana, could justify their own violation of the Act by invoking an asserted constitutional right of individuals to smoke marijuana in certain circumstances, there is, in actuality, no fundamental right to use an unapproved drug for medical treatment. See *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (per curiam) (Laetrile); *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.) (Laetrile), cert. denied, 449 U.S. 937 (1980); *United States* v. *Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-1314 (5th Cir. 1987) (antineoplastons), cert. denied, 484 U.S. 1065 (1988); cf. *Washington* v. *Glucksberg*, 521 U.S. 702, 723, 728 (1997) (no fundamental due process right to assisted suicide). Similarly, the courts of appeals have uniformly rejected constitutional challenges to Congress's classification of marijuana as a schedule I drug. See *Greene*, 892 F.2d at 455-456; *United States* v. *Fry*, 787 F.2d 903, 905 (4th Cir.), cert. denied, 479 U.S. 861 (1986); *Fogarty*, 692 F.2d

d. Finally, the recognition of a "medical necessity" defense is inconsistent with the fact that marijuana has not been approved by the FDA based upon a showing that marijuana is safe and effective for *any* medical use. See 21 U.S.C. 321(p), 355. In the 1998 legislation, Congress expressed its continuing adherence to the existing FDA drug approval process by stating that "marijuana * * * has not been proven safe and effective for medical purposes" and that marijuana has "not been approved by the [FDA] to treat any disease or condition." 112 Stat. 2681-760 to 2681-761.[15]

The provision's sponsor, Representative McCollom, explained that the 1998 "statement is important" because, *inter alia*, "[m]ore than 30 States and the District of Columbia have been targeted for possible medical marijuana initiatives," and that such initiatives "have already been passed in California and Arizona." 144 Cong. Rec. H7720 (daily ed. Sept. 15, 1998); see also *id.* at S10,666 (daily ed. Sept. 21, 1998). Congress therefore expressed not only its continuing support for the "existing Federal legal process for determining the safety and efficacy of drugs," but also its opposition to "efforts to circumvent this process by legalizing

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at 547-548 & n.4; *Middleton*, 690 F.2d at 822-823; *Kiffer*, 477 F.2d at 352-357.

[15] Respondents argue (Br. in Opp. 20) that the 1998 legislation "does not have the force of law." Respondents ignore the fact that Congress *already* has barred the unauthorized distribution of marijuana for *all* purposes. The 1998 Act expressly confirms that preexisting prohibition specifically with respect to the use of marijuana for asserted medical purposes. See generally *Accardi* v. *Pennsylvania R.R.*, 383 U.S. 225, 229 (1966) (continuing purpose of Congress reflected in "sense of the Congress" enactment); *Harris* v. *United States*, 359 U.S. 19, 22 n.8 (1959) (continuing purpose of Congress reflected in subsequently-enacted legislation).

marijuana * * * *for medicinal use* without valid scientific evidence and the approval of the Food and Drug Administration." 112 Stat. 2681-761 (emphasis added). The 1998 Act thus refutes the notion that courts and juries may allow the federally-unregulated distribution of marijuana based on a common law principle that Congress would have sanctioned such distribution had it considered the competing values at stake.

3. In *United States* v. *Rutherford*, 442 U.S. 544 (1979), this Court considered a highly analogous issue and held that a claim of medical need for a drug cannot override Congress's legislative judgment that the drug not be distributed absent a finding by the FDA under the FDCA that the drug is safe and effective. In *Rutherford*, a class of terminally ill cancer patients and their spouses brought suit to enjoin the government from interfering with the interstate shipment and sale of Laetrile, a drug that had not been approved by the FDA. The district court granted the requested relief, and the Tenth Circuit affirmed, holding that the safety and effectiveness protections of the FDCA had no reasonable application to terminally ill cancer patients because those patients, by definition, would die of cancer regardless of their treatment. *Id.* at 548-549.

This Court unanimously reversed. The Court rejected the Tenth Circuit's determination that an exemption from the Act was justified because the safety and effectiveness standards could have no reasonable application to terminally ill cancer patients, explaining that, "[u]nder our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. * * * Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." 442

U.S. at 555, 559. The Court also reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is incumbent upon the courts to give it effect. *Id.* at 551.

Finally, the Court reasoned that the recognition of a non-statutory exception to the federal drug laws could wreak havoc on Congress's aim to avert the dangers associated with the unregulated use and distribution of unapproved drugs:

> It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked.

442 U.S. at 557-558.

The Court's holding and reasoning in *Rutherford* apply with equal force in this case, where Congress has expressed its unambiguous intent in the CSA to ban the unauthorized distribution of marijuana, even for medical purposes. By sanctioning the ongoing and open violation of the federal drug laws, the court of appeals' decision opens the way for manufacturers, distributors, or users of other schedule I drugs (such as heroin or LSD)—which have not been approved by the FDA for *any* medical use and which are controlled under the CSA because of their "high potential for abuse" and "lack of accepted safety for use" even "under medical supervision"—to invoke "medical necessity" as a defense to a violation of the nation's drugs law. The re-

cognition of a "medical necessity" defense under the CSA therefore would significantly undermine the Act's paramount policy to protect the public health and safety. See 21 U.S.C. 801(2).

4. Respondents contend (Br. in Opp. 6, 21-22, 25-29) that Congress's determination that marijuana has no accepted medical use is harmonious with their unregulated distribution of marijuana because the statutory phrase "currently accepted medical use in treatment" (21 U.S.C. 812(b)(1)(B)) serves a different purpose than that served by the common law defense of "medical necessity." Respondents reason (Br. in Opp. 26, 28) that Congress placed marijuana in schedule I to restrict its distribution to the "general public," while a "medical necessity" defense permits the distribution of marijuana only when patients and their physicians "jointly agree" that "generally accepted treatments are ineffective." Those contentions are legally irrelevant and, in any event, are fundamentally mistaken.

a. It is precisely because Congress has determined that marijuana has no "currently accepted medical use" and placed that drug in schedule I that Congress has emphatically foreclosed a distributor from ignoring the CSA on the ground that the recipients claim a medical need to smoke marijuana. Thus, the CSA imposes an absolute ban on the distribution of marijuana—*including* distribution for asserted medical purposes—outside the strict confines of the Act itself. See pp. 19-20, *supra*. And even for drugs listed in schedules II through V, which Congress or the Attorney General has determined *do* have an accepted and safe medical use, 21 U.S.C. 812(b)(2)-(5), and for which the CSA *does* permit physicians to determine whether particular patients have a medical need for the drug, 21 U.S.C. 829, the CSA imposes strict controls on physicians and phar-

macies before they may distribute or dispense the drug. See pp. 20-23, *supra*. That comprehensive set of statutory controls leaves no room for the distribution of marijuana for asserted medical purposes by relying on a common law defense of necessity.

b. In any event, the notion that respondents may dispense marijuana for medical use *is* inconsistent with the CSA's determination that marijuana has no "currently accepted medical use" (21 U.S.C. 812(b)(1)(B)), as well as the absence of a finding by the FDA under the FDCA that marijuana is "safe and effective" for *any* intended medical use (21 U.S.C. 355). See also 112 Stat. 2681-760 (finding that marijuana is "unsafe, even under medical supervision"; "lack[s] any currently accepted medical use"; and has never been approved by the FDA as "safe and effective" "to treat any disease or condition"). Respondents cannot credibly maintain that Congress intended to permit defendants charged with violating the CSA to persuade courts and juries that smoking marijuana "has proven effective in relieving [patients' medical] conditions or symptoms" (Br. in Opp. 22) when Congress already has most emphatically determined that marijuana, in fact, has *not* been "proven" to be safe or effective to treat any medical condition.[16]

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[16] Nor is it plausible to suggest (Br. in Opp. 26-29) that recognition of a "medical necessity" defense would be confined to a limited number of individuals or class of medical conditions. For instance, on May 19 and October 22, 1997, two undercover DEA agents purchased marijuana from respondents by presenting phony physician statements asserting that the agents suffered from post-traumatic stress disorder and menstrual cramps. J.A. 48, 70. Moreover, on May 21, 1998, approximately 200 persons visited OCBC to obtain marijuana to treat a wide variety of conditions, including AIDS, cancer, glaucoma, pain, headaches,

c. Similarly, to allow courts and juries to consider whether marijuana is medically "efficacious" or consistent with "good medical practice" for a given individual (Br. in Opp. 28, 29) would subvert Congress's intent to bar the medical use of a schedule I drug until rigorous scientific proof establishes that the drug no longer meets the statutory criteria for listing under that schedule. Before marijuana may be removed from schedule I, the Attorney General, in consultation with the Secretary of HHS, must determine that marijuana has a "currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B). In making that determination, the Attorney General and the Secretary must consider the "[s]cientific evidence of [drug's] pharmacological effect" and "state of current scientific knowledge regarding the drug." 21 U.S.C. 811 (c)(2) and (3).

Applying those provisions, in 1992, the DEA Administrator concluded in response to a petition to reschedule marijuana that marijuana has no currently accepted medical use and therefore should not be transferred to schedule II. 57 Fed. Reg. 10,499. The Administrator also delineated the five characteristics that a drug must have in order to find that it has a currently accepted

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arthritis, rotator cuff syndrome, stress, depression, paranoid schizophrenia, and anxiety. See J.A. 32-39. Similarly, in requesting the district court to modify its injunction in light of the Ninth Circuit's decision, respondents submitted the affidavits of persons who asserted that they used marijuana for medical conditions such as lupus, irritable bowel syndrome, cystitis, cancer, arthritis, insomnia, Hepatitis C, AIDS, scoliosis, esophageal stricture, Meniere's disease, sarcoidosis, leg and back spasms, migraine headaches, depression, and bulimia. Vol. 1 Declarations in Support of Defendants' Motion to Dissolve or Modify Preliminary Injunction Order (filed May 30, 2000).

medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate studies proving the drug's safety in treating a specific, recognized disorder; (3) there must be adequate and well-controlled studies proving the drug's efficacy in treating a specific, recognized disorder; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *Id.* at 10,506. Based on a consideration of those five factors, as well as the lack of reliable scientific evidence supporting the medical use of marijuana for any medical condition, *id.* at 10,500-10,505, the Administrator concluded that "[m]arijuana fails all five points of the test." *Id.* at 10,507.

The Administrator also addressed the testimony of individuals and physicians who opined that marijuana had a medical use, explaining that "[l]ay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof" do not provide a sufficiently reliable basis under the CSA for assessing the safety and efficacy of marijuana or any other drug. 57 Fed. Reg. at 10,505. The Administrator's determinations were upheld by the District of Columbia Circuit, which concluded that the Administrator reasonably insisted on "rigorous scientific proof over anecdotal evidence, even when reported by respected physicians." *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (1994). The court of appeals also reasoned that the Administrator had properly relied on "the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies," and that "[t]he Administrator reasonably accorded more weight to the opinions of these experts than to the anecdotal

testimony of laymen and doctors." *Ibid.* The court of appeals therefore concluded that the Administrator's "findings are consistent with the view that only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." *Ibid.*

Congress in the FDCA similarly has rejected reliance on the subjective views of individual physicians and patients to support the use of a new drug, such as marijuana, for medical use. The FDCA requires that, before the FDA may approve a new drug, the drug must be proven safe through "adequate tests by all methods reasonably applicable" and proven effective based on "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. 355(d); accord 112 Stat. 2681-760 (new drug "must meet extensive scientific and medical standards established by the [FDA] to ensure it is safe and effective"). The FDA therefore will not consider "[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation." 21 C.F.R. 314.126(e); see *Rutherford*, 442 U.S. at 550 n.7 (The FDCA requires "an 'expert consensus' on safety and effectiveness founded upon 'substantial evidence' as defined in [21 U.S.C. 355(d)]."); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (The FDA's "strict and demanding standards," which "bar[] anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by the legislative history" of the FDCA, which reflects "a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.").

At bottom, the recognition of a "medical necessity" defense would bypass altogether the statutory pro-

cedures that Congress enacted for the rescheduling of a drug by the Attorney General and for the approval of a drug by the FDA, in favor of a judicially sanctioned system in which individual patients, physicians, and cannabis clubs decide whether marijuana is safe and effective for medical use. Congress plainly did not intend to permit a result that would render so "wholly nugatory" (*Bailey*, 444 U.S. at 416 n.11) the statutory framework of the CSA.

5. Respondents assert (Br. in Opp. 18) that the CSA's history shows that "Congress placed cannabis only tentatively in Schedule I" because Congress "did not have a firm understanding of cannabis." Respondents observe (*id.* at 18-20) that the House Report stated that "[t]he extent to which marihuana should be controlled is a subject upon which opinions diverge widely" (H.R. Rep. No. 1444, *supra*, Pt. 1, at 12); that the Secretary of Health, Education, and Welfare recommended to Congress that marijuana "be retained within schedule I" until the completion of further studies (*id.* at 13); and that a Commission established by Congress recommended the decriminalization of casual distribution of small amounts of marijuana for no remuneration or insignificant remuneration not involving profit (National Comm'n on Marihuana & Drug Abuse, *Marihuana: A Signal of Misunderstanding* 152 (Mar. 1972) (*Marihuana*)).[17] Nothing in that history,

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[17] The Commission explained that many users of marijuana had been given the drug by a "friend, acquaintance or family member," and that such "casual transfers" should be treated "as the functional equivalent of possession." *Marihuana* 157, 158. The Commission also recommended that there should be no federal criminal sanction for possession of marijuana for personal use, reasoning that federal agencies "have left possession enforcement to the states * * * to maximize the use of [federal] enforcement re-

however, casts doubt on the fact that Congress placed marijuana in schedule I, where it has been listed for 30 years, knowing full well that it was categorically banning the distribution of marijuana for any purpose, including asserted medical uses, except as authorized by the CSA. See H.R. Rep. No. 1444, *supra*, Pt. 1, at 13 ("marihuana is listed under schedule I, as subject to the most stringent controls under the bill"); see also 116 Cong. Rec. 1664 (1970) (statement of Sen. Hruska) (noting that marijuana was placed in schedule I because it "comes squarely within the criteria of that schedule," *i.e.*, "highest abuse potential" and "little or no accepted medical use in this country").

We do not dispute that Congress contemplated the possibility that further research could produce scientific evidence that would support the use for medical purposes of certain substances, including marijuana, that Congress initially listed in schedule I. But Congress directed that, to be credited and given weight under the CSA, any such research must be presented, not to organizations like OCBC, or to courts and juries in individual proceedings brought by the United States to enforce the CSA, but to the Attorney General and the Secretary of HHS to consider under the exclusive standards and administrative procedures set forth in the CSA itself. 21 U.S.C. 811, 812; see pp. 23-25, *supra*.[18]

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sources for major priorities," such as eliminating marijuana traffickers and suppliers. *Id.* at 155-156. Notwithstanding the Commission's recommendations, Congress in the CSA has maintained criminal penalties for both the possession of marijuana and the casual distribution of marijuana that does not involve profit. See 21 U.S.C. 841(a)(1), 844(a).

[18] There is no petition pending before the DEA to reschedule marijuana on the ground that marijuana has any accepted medical use. Cf. note 12, *supra*. We do note, however, that studies are

The history of the CSA therefore provides no basis whatsoever for inferring a congressional intent to permit the distribution of marijuana outside the framework of the CSA, based on an asserted medical need to smoke it.

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underway that involve the human health effects of marijuana. We are informed by the DEA that two researchers are currently registered with the DEA to conduct clinical research under 21 U.S.C. 823(f) into the human health effects of smoked marijuana. Moreover, on May 21, 1999, HHS announced new guidance for the provision of marijuana for medical research. See *Kuromiya* v. *United States*, 78 F. Supp. 2d 367, 374 (E.D. Pa. 1999). We also note that, in 1999, the Institute of Medicine reviewed the existing scientific evidence concerning possible medical uses of marijuana and recommended that further research be devoted, not to developing marijuana as a licensed drug, but to developing a method of delivering cannabinoids without the serious adverse health consequences associated with smoking marijuana. See Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* 10-11 (Janet E. Joy et al. eds. 1999) (noting that "[b]ecause marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use," and recommending "clinical trials * * * to serve as a first step toward the development of nonsmoked rapid-onset cannabinoid delivery systems"). One method of delivery of cannabinoids currently available is Marinol®, which contains a synthetic form of THC in pill form. Marinol® has been approved by the FDA for the treatment of nausea and vomiting associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in AIDS patients. See 64 Fed. Reg. 35,928 (1999). On July 2, 1999, DEA transferred Marinol® from schedule II to schedule III, thereby lessening the regulatory restrictions on its use. *Ibid.*

B. Courts Lack The Equitable Discretion Under The CSA To Permit The Unauthorized Distribution Of Marijuana To Persons Who Assert A Medical Necessity To Use It

1. In holding that "medical necessity" is a "legally cognizable defense" (App. 8a), the court of appeals did not attempt to reconcile a "medical necessity" defense either with the text, structure, or purposes of the CSA, or with the 1998 legislation disapproving any attempt to legalize marijuana for medicinal use outside the existing framework of the CSA and the FDCA. Rather, the court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought" under 21 U.S.C. 882(a). App. 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)). The court of appeals took the view that the district court abused its discretion first in failing to consider what the court of appeals identified as "a strong public interest" in the availability of marijuana for medicinal purposes, and second in finding that an injunction against marijuana distribution could not be supported by the government's "general interest in enforcing its statutes." *Id.* at 9a, 11a.

Those conclusions, however, conflict with this Court's precedents concerning the limits of a district court's equitable discretion in fashioning an injunction. This Court has long held that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937); see also *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405, 417

(1975) ("when Congress invokes the Chancellor's conscience to further transcendent legislative purposes, what is required is the principled application of standards consistent with those purposes and not 'equity [which] varies like the Chancellor's foot'").

Those principles were reaffirmed in *TVA* v. *Hill*, 437 U.S. 153 (1978), in which this Court held that, in examining whether to enter injunctive relief, a court must be mindful that

> it is * * * emphatically * * * the exclusive province of the Congress not only to formulate legislative policies and mandate programs and projects, but also to establish their relative priority for the Nation. Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.

Id. at 194.[19] The Court similarly has explained that although it will "not lightly assume that Congress meant to restrict the equitable powers of the federal courts," "where Congress has made its intent clear, '[the Court] must give effect to that intent.'" *Miller* v. *French*, 120 S. Ct. 2246, 2253 (2000) (quoting *Sinclair Refining Co.* v. *Atkinson*, 370 U.S. 195, 215 (1962)); see also *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 313 (1982) ("[A] statute in so many words, or by a necessary and inescapable inference, [may] restrict[] the court's

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[19] One commentator has explained that *Hill* "established that a court cannot use equitable discretion as a pretext for reordering priorities that Congress already has set." Daniel A. Farber, *Equitable Discretion, Legal Duties, and Environmental Injunctions*, 45 U. Pitt. L. Rev. 513, 519 (1984).

jurisdiction in equity.") (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)).

In similar circumstances, this Court in *Rutherford* (discussed at pp. 27-28, *supra*) held that the Tenth Circuit erred in holding that a district court had the power to enter an injunction permitting the use of an unapproved drug (Laetrile) by terminally ill cancer patients, even under a doctor's supervision, because the FDCA "makes no special provision for drugs used to treat terminally ill patients." 442 U.S. at 551.[20] The CSA similarly "makes no special provision" for the unauthorized distribution of drugs for medical use, no matter how fervently individual patients or doctors believe that a drug has a medical use. Congress already has considered the public interest, balanced the relevant medical and other policy considerations, and made the fundamental policy choice that "[t]he illegal * * * distribution[] and * * * improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). Congress therefore has concluded that, unless and until the Attorney General removes marijuana from schedule I, the drug has no accepted medical or safe use and may not be distributed outside of a strictly controlled research project under the CSA. See pp. 19-20, *supra*. A district court therefore lacks the discretion, based on its own perception of the public interest and its own weighing of possible medical bene-

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[20] Indeed, the Court in *Rutherford* cited *Hill* with approval, observing that "[e]xceptions to clearly delineated statutes will be implied only where essential to prevent absurd results or consequences obviously at variance with the policy of the enactment as a whole." 442 U.S. at 552 (internal quotation marks omitted); accord *id.* at 555.

fits against the potential for abuse, to craft an injunction under the CSA that exempts from the injunction's reach the distribution of marijuana for medical use.

2. In defending the judgment of the court of appeals, respondents argue (Br. in Opp. 13-17) that a court may decline to enjoin a cannabis distribution club from distributing marijuana in blatant violation of the CSA, whether or not "medical necessity" is a valid defense under the Act. Not even the court of appeals, however, embraced that radical proposition. See App. 8a (finding that the district court failed to "take into account a legally cognizable defense that likely would pertain in the circumstances").[21]

Nor is such a proposition supported by any decision of this Court. As previously explained, district courts sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.*, 300 U.S. at 551; see also *Miller*, 120 S. Ct. at 2253; *Hill*, 437 U.S. at 194. Respondents therefore erroneously rely on this Court's decisions in *Romero-Barcelo*, *supra*, and *Hecht Co.* v. *Bowles*, 321 U.S. 321 (1944). Those decisions confirm that a court may not exercise its equitable discretion—which is intended to allow a court to decide how best to assure *compliance* with a congressional act—so as to countenance ongoing *violation* of a congressional act.

In *Romero-Barcelo*, the Court held that under the Federal Water Pollution Control Act, the district court retained discretion in appropriate circumstances to

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[21] The district court's modification of its injunction likewise was premised only on the assumption that, because "medical necessity" is a valid defense under the CSA, a district court has the equitable power to permit the medical use of marijuana in violation of the CSA. App. 13a.

order relief other than an immediate injunction barring all discharge of pollutants that did not comply with the Act if that other relief would "achieve compliance" with the Act. 456 U.S. at 307. The district court found that the Navy had committed "technical violations" of the statute, without "causing any 'appreciable harm' to the environment," by occasionally discharging ordnance into the sea without a permit. *Id.* at 310. The district court ordered the Navy to apply for the requisite permit, but declined to enjoin naval operations, concluding that an injunction was not necessary to ensure compliance. *Ibid.* This Court found that "although the District Court declined to enjoin the discharges, it neither ignored the statutory violation nor undercut the purpose and function of the permit system." *Id.* at 315. The Court further observed that, "[r]ather than requiring a district court to issue an injunction for any and all statutory violations, the FWPCA permits the district court to order that relief it considers necessary *to secure prompt compliance with the Act.*" *Id.* at 320 (emphasis added).

Similarly, in *Hecht Co.*, the district court declined the government's request for an injunction against a defendant that had violated statutory price controls. The district court reasoned that it had "no doubt" that the defendant acted in "good faith and diligence" in attempting to comply with the statute, that the defendant had taken "vigorous steps" to correct and prevent recurrence of its mistakes, and that issuance of an injunction would have "no effect" on ensuring future compliance with the statute. 321 U.S. at 325, 326. This Court concluded that under the statute "there is some room for the exercise of discretion on the part of the court," and further observed that other remedial orders short of injunction might have been consistent with the

statute. *Id.* at 328. The Court made clear, however, that courts have the responsibility to enforce the statute and that "their discretion under [the statute] must be exercised in light of the large objectives of the Act," "[f]or the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief." *Id.* at 331.[22]

Those decisions therefore provide no support for a district court, under its authority "to *enjoin* violations" of the CSA, 21 U.S.C. 882(a) (emphasis added), to *allow* the ongoing illegal distribution of marijuana, based on the court's perception that the public interest supports the use of marijuana for medical purposes. As we have explained, Congress already has weighed what it deemed to be the relevant public-interest considerations and categorically determined that marijuana may

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[22] Contrary to respondents' suggestion (Br. in Opp. 17), *Amoco Production Co.* v. *Village of Gambell*, 480 U.S. 531 (1987), likewise does not support the invocation of a district court's equitable power to permit respondents to distribute marijuana in violation of the CSA. The Court in *Amoco* held that a district court did not err in declining to issue an injunction to bar exploratory drilling on Alaskan public lands, because the district court's decision "did not undermine" the policy of the Alaska National Interest Lands Conservation Act, 16 U.S.C. 3120, "to protect Alaskan subsistence resources from unnecessary destruction." 480 U.S. at 544, 546. The Court reasoned that the exploration activities would not significantly restrict the subsistence uses of the land; that the denial of injunctive relief did not deprive the government of its ability to control and shape the leasing process; and that Congress had expressed a policy favoring continued oil exploration in another federal statute. *Id.* at 544-545. Nothing in the Court's decision in *Amoco* suggests that a court may use its equity power to determine that the public interest supports conduct that is fundamentally antithetical to the text, structure, and policy of the statute that the court is supposed to enforce.

not be distributed for any purpose, "[e]xcept as authorized" by the Act, 21 U.S.C. 841(a)(1). Congress therefore has "deliberately expressed" (*Virginian Ry.*, 300 U.S. at 551) its intention to foreclose a district court from using the power conferred under 21 U.S.C. 882(a) to permit the ongoing and illegal distribution of marijuana for asserted medical purposes.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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RESTATED QUESTIONS PRESENTED

1. Did Congress limit the traditional equitable powers of the federal courts to consider the public interest in shaping injunctive relief under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*?

2. Did Congress abrogate the traditional common law defense of necessity under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*?

3. Does Congress have the power to foreclose wholly intrastate access to the only medication that will avoid death, intractable pain, starvation or blindness of seriously ill patients participating in a state-sponsored emergency medical program?

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STATUTES AND CONSTITUTIONAL PROVISIONS

Sections 811, 812(b), and 882(a) of Title 21 of the United States Code are reprinted at App. 83a-89a.[1] Sections 801 and 903 of Title 21 of the United States Code and the Fifth, Ninth, and Tenth Amendments to the United States Constitution are reprinted in an appendix attached hereto.

STATEMENT OF FACTS

In November 1996, California voters enacted an initiative measure entitled the Compassionate Use Act of 1996 (Proposition 215), to permit seriously ill patients and their primary caregivers to possess and cultivate cannabis with the approval or recommendation of a physician. Cal. Health and Safety Code § 11362.5. The physician must determine "that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief." *Id.* § 11362.5(b)(1)(A).[2]

To implement the will of California voters, Respondents organized a Cooperative to provide seriously ill patients with a safe and reliable source of medical cannabis. A physician serves as Medical Director, and registered nurses staff the Cooperative during business hours.

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[1] "App." refers to the Appendix filed by Petitioner with the Petition for a Writ of Certiorari.

[2] Although the district court assumed that Respondents' conduct complied with state law (App. 47a), Petitioner wrongly asserts that Proposition 215 does not authorize distribution of cannabis. Pet.Br. 8 n.6. The City of Oakland established its Distribution Program with the Cooperative to fulfill the initiative's mandate to governments to "implement a plan to provide for safe and affordable distribution of marijuana to all patients in need of marijuana." Cal. Health & Safety Code § 11362.5(b)(1)(C).

J.A. 24-25.[3] The Cooperative's Protocols, revised March 30, 1998, require prospective members to provide a written statement from a treating physician assenting to cannabis therapy, and submit to a screening interview by staff and verification of the physician's approval. Patients accepted as members receive identification cards.

The Cooperative, a not-for-profit organization, operates in downtown Oakland, in cooperation with the City of Oakland and its police department. No smoking is permitted on the premises. J.A. 2-3, 9-10, 23-24, 148, 150-151, 153. On July 28, 1998, the City of Oakland adopted, by ordinance, a Medical Cannabis Distribution Program, and on August 11, 1998, officially designated the Cooperative to administer the City's program. J.A. 138-46.[4]

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[3] "J.A." refers to the Joint Appendix filed in this Court.

[4] The government quotes from the 1997 declarations of DEA agents to suggest that the distribution of cannabis to patients demonstrating necessity under the amended injunction would not be subject to "strict controls" by the City of Oakland. Pet.Br. 22-23 n.11, 30-31 n.16. Respondents categorically deny numerous assertions in the agents' declarations. The agents presented phony physician's statements to gain admission in May and October, 1997. J.A. 46-51, 68-73. The agents also misrepresented themselves as primary caregivers for members who were too sick to come in (J.A. 65) and set up phone lines where agents posed as physicians' staff to provide telephone verification of the phony physician's statements. J.A. 78-79. This activity *predated* the establishment of the City of Oakland's Medical Cannabis Distribution Program by more than one year, and predated by three years the amended injunction, which itself establishes strict controls over which patients may establish legal necessity. Implementation of the amended injunction would remain under the continuing jurisdiction of the district court, which retains the authority to punish any violations as contempt. The threat of immediate contempt sanctions, of course, vastly exceeds the normal control mechanisms of the CSA.

On January 9, 1998, the United States sued in the United States District Court for the Northern District of California, seeking to enjoin Respondents from distributing cannabis to patient-members. On May 19, 1998, the district court issued a preliminary injunction enjoining Respondents from "engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute marijuana, in violation of 21 U.S.C. § 841(a)(1)." App. 39a-40a. In so doing, the district court rejected a "blanket" assertion of medical necessity, but specifically left this justification open for later consideration on an individual basis. App. 70a-71a.

On October 13, 1998, the district court held Respondents in contempt of the preliminary injunction. The district court rejected a necessity defense, finding that only four patients to whom cannabis was allegedly distributed on the day covered by the Order to Show Cause submitted evidence sufficient to determine legal necessity under *United States v. Aguilar*.[5] App. 29a-32a. The district court then modified the injunction to permit the U.S. Marshal to seize Respondents' offices. App. 37a. Respondents thereafter informed the district court that they would comply with the injunction. Order re Ex Parte Motion at p.2 filed Oct. 30, 1998. Respondents moved for a modification of the injunction to permit distribution of cannabis to the limited number of patients who could demonstrate necessity under the *Aguilar* standard and

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[5] In *United States v. Aguilar*, 883 F.2d 662, 693 (9th Cir. 1989), the court reaffirmed the following elements of a necessity defense:

> (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relationship between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law.

submitted numerous declarations in support of their motion. The district court denied that motion. App. 7a.

On October 27, 1998, the Oakland City Council adopted a resolution declaring a public health emergency, finding that the closure of the Cooperative "impairs public safety by encouraging a market for street narcotic peddlers to prey upon Oakland's ill residents" and that the closure will cause pain and suffering to thousands of seriously ill persons. The resolution urged the federal government to desist from any and all actions that pose obstacles to access to cannabis for Oakland residents whose physicians have determined that their health will benefit from the use of cannabis. J.A. 149-50. The City Council renews that resolution every two weeks. *E.g.*, J.A. 152-57.

On September 13, 1999, the Court of Appeals reversed the district court's denial of the motion to modify and remanded the case to the district court, holding that (1) the court could take into account a legally cognizable defense of necessity in considering the proposed modification (App. 8a), (2) in exercising its equitable discretion, the court must expressly consider the public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of persons with serious or fatal illnesses, and (3) the record before the district court justified the proposed modification. App. 9a-10a.[6] The government's petition for rehearing and rehearing en banc was denied on February 29, 2000, without a single judge even requesting to vote for rehearing. App. 82a.

On remand, Respondents renewed their motion to modify the preliminary injunction, submitting more declarations to establish that patient-members could meet all

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[6] The Court of Appeals dismissed Respondents' appeal of the contempt order as moot, on the grounds the contempt was purged. App. 5a.

of the *Aguilar* requirements for a claim of necessity. The evidence established that:

(1) Some patient-members face a choice of evils, requiring them to violate the law to gain relief from debilitating pain, life-threatening illness, or loss of sight. Patients described the agony of suffering from HIV/AIDS and its "wasting syndrome" (Decls. of Alcalay, J.A. 20; Dunham, J.A. 86; Stogdell, J.A. 89), nausea, loss of appetite, and dramatic weight loss accompanying cancer treatment (Decls. of Bonardi, J.A. 80; Beal, J.A. 84; Frost, J.A. 91), and pain and deteriorating field of vision from glaucoma (Sweet Decl., J.A. 93.)

(2) Those patient-members will suffer imminent harm if deprived of cannabis, including loss of life (Decls. of Alcalay, J.A. 22; Beal, J.A. 84), starvation (Decls. of Bonardi, J.A. 82; Stogdell, J.A. 89), and blindness (Sweet Decl., J.A. 94.)

(3) There is a direct, causal relationship between patient-members' use of cannabis and averting imminent harm. For example, Dr. Marcus Conant, M.D., who has treated 5,000 HIV-infected men and women, states:

> In my practice, marijuana has been of greatest benefit to patients with wasting syndrome. I do not routinely recommend marijuana to my patients, nor do I consider it the first line of defense against AIDS-related symptoms. However, for some patients, marijuana proves to be the *only* effective medicine for stimulating appetite and suppressing nausea, thus allowing the AIDS patient to recover lost body mass and become healthier.

J.A. 101.[7] Dr. Howard MacCabee, M.D., who directs the Radiation Oncology Center, and treats 2,000 patients in various stages of radiation therapy for cancer, states:

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[7] The Joint Appendix erroneously states that the district court never acted upon Respondents' request for judicial notice

> Because of the nature of some cancers, I must sometimes irradiate large portions of my patient's abdomens. Such patients often experience nausea, vomiting, and other side effects. Because of the severity of these side effects, some of my patients choose to discontinue treatment altogether, even when they know that ceasing treatment could lead to death. . . . I have witnessed cases where patients suffered from nausea or vomiting that could not be controlled by prescription anti-emetics. . . . As a practical matter, some patients are unable to swallow pills because of the side effects of radiation therapy or chemotherapy, or because of the nature of the cancer (for instance, throat cancer). For these patients, medical marijuana can be [an] effective form of treatment.

J.A. 110-11. Additionally, Dr. Lester Grinspoon, M.D., a leading researcher on the use of cannabis for medical purposes, and author of 154 scholarly articles and 13 books on related subjects, summarized the published scientific evidence establishing the efficacy of cannabis as an anti-emetic for cancer chemotherapy, as a retardant to reduce intraocular pressure experienced by glaucoma sufferers, as an anticonvulsant to control seizures, as an analgesic to control pain, and as an appetite stimulant to combat the AIDS wasting syndrome. J.A. 118-37; *see also* Decl. of Dr. Morgan, J.A. 113-115.

(4) There are no legal alternatives to cannabis for these patients. They described how they had tried alternative medications available by prescription, including the synthetic THC pill known as "Marinol," and found them ineffective. J.A. 22, 90, 92. Dr. Conant, who served as one of the principal investigators when Marinol was approved by the FDA, testified:

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of the declarations of Doctors Conant and MacCabee. J.A. II n.**. The motion was granted on October 13, 1998. App. 24a.

> . . . Marinol (like any medication) is not effective in treating all patients. In some cases, the reason is simple: Marinol is taken orally, in pill form. Patients suffering from severe nausea and retching cannot tolerate the pills and thus do not benefit from the drug. There are likely other reasons why smoked marijuana is sometimes more effective that Marinol. The body's absorption of the chemical may be faster or more complete when inhaled.

J.A. 104-05. *See also* J.A. 113-15 and 132-33.

The government submitted no evidence in opposition, nor did it challenge Respondents' evidentiary showing. Instead the government relied upon its legal argument that a necessity defense was not available under the Controlled Substances Act (the "CSA"). On July 17, 2000, the district court modified the preliminary injunction to exempt the distribution of cannabis to patient-members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if denied access to cannabis, (3) need cannabis to treat or alleviate the medical condition or its associated symptoms, and (4) have no reasonable legal alternative to cannabis for effective treatment or alleviation of symptoms, because all other legal alternatives have been tried and were ineffective or intolerable. App. 16a-17a.

On July 25, 2000, the government noticed an appeal from the district court's order modifying the injunction. That appeal has been fully briefed and awaits argument before the Court of Appeals, which suspended proceedings to await this Court's ruling. On August 29, 2000, this Court granted the government's request for a stay of the July 17 order, "pending final disposition of the appeal by the United States Court of Appeals for the Ninth Circuit and further order of this Court." *United States v. Oakland Cannabis Buyers' Cooperative*, 121 S. Ct. 21 (2000). On November 27, 2000, this Court granted the government's

petition for writ of certiorari to review the Court of Appeal's September 13, 1999 decision.

SUMMARY OF ARGUMENT

With heated rhetoric, the government urges that the Court of Appeals' ruling in this case will significantly impair its enforcement of the CSA "against drug traffickers who are acting under the guise of 'medical necessity,' " and an *amicus* characterizes Respondents as stealthy subversives whose real agenda is back-door legalization of recreational drug use. Cert. Reply Br. 4-5; *Amicus* Br. of Family Research Council 4-5, 26-28. The Court should note, however, that the government declined to present any evidence of any potential threat that modification of the injunction might allegedly pose to the public interest when invited to do so by the district court in these proceedings. App. 13a. In other proceedings, the district court found government fears that the medical use of cannabis would create a significant drug enforcement problem were "exaggerated and without evidentiary support." *Conant v. McCaffrey*, 172 F.R.D. 681, 694 n.5 (N.D. Cal. 1997).

The citizens of every state in which this issue has appeared on the ballot, and the thousands of physicians who have concluded that scientific evidence supports the conclusion that cannabis has legitimate therapeutic value, are not "drug traffickers" or renegades. They now include the National Institute of Medicine,[8] as well as the

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[8] *Marijuana and Health: Assessing the Science Base*, A Report Prepared for the National Institute of Medicine at the request of the White House Office of National Drug Control Policy (1999). The report concludes that despite the risks associated with smoking, smoked cannabis may be the best alternative available for some patients. *Id.* at 177. Many of Respondents' patients ingest cannabis by means other than smoking, e.g., vaporization, tincture, compress, and salve.

New England Journal of Medicine, which states "that a federal policy that prohibits physicians from alleviating suffering by prescribing marijuana for seriously ill patients is misguided, heavy-handed, and inhumane." Jerome Kassirer, *Federal Foolishness and Marijuana*, New Eng. J. of Medicine (Jan. 30, 1997) at 366. The nine states that have rejected this policy are not defying the federal government. In enacting the CSA, Congress clearly expressed its intention to leave the states free to exercise their independent authority over public health:

> No provision of this subchapter shall be construed as indicating an intention on the part of Congress to occupy the field . . . unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. California's Compassionate Use Act and the CSA *can* consistently stand together, at least in the narrow canyons created by the equitable discretion of federal courts and the common law doctrine of necessity. The limited exception crafted by the district court would allow a small group of patients who need medical cannabis to avert imminent harm such as death, starvation, or blindness.[9]

The resolution of this case does not require a broad ruling by this Court that medical necessity may be asserted as a defense in any prosecution for violation of the CSA. To affirm the court below, this Court need only hold that where the government invokes the equity jurisdiction of the federal courts by seeking injunctive relief, the federal courts have discretion to limit that relief by balancing the government's need against the hardships

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[9] Although two-thirds of Respondents patient-members suffer from AIDS or related disorders, and many are undergoing treatment for cancer, only 14 members (fewer than 2/10 of one percent) qualify under the rigorous standards established by this exception. App. 16a-17a.

imposed upon the Respondents. This Court can leave the amended injunction in place, and let the resolution of the availability of a defense of medical necessity await the government's criminal prosecution of a defendant who offers evidence to support the defense.

Should this Court choose to address the availability of a medical necessity defense, Respondents contend that the CSA does not foreclose this defense. As with other common law defenses such as duress and entrapment, the necessity defense is implicit in a sensible construction of the CSA to avoid injustice, oppression, or absurd consequences. *United States v. Kirby*, 7 Wall. 482, 486-87 (1869); *Sorrells v. United States*, 287 U.S. 435, 451 (1932). The placement of marijuana on Schedule I of the CSA reflects no Congressional finding that cannabis has no medical use, or that it can never serve any legitimate medical purpose. Government acquiescence in medical use by selected patients who have demonstrated medical necessity confirms that such use is not inconsistent with the CSA, and parallel provisions of the Uniform Controlled Substances Act also have been widely applied to permit compassionate use by patients demonstrating medical necessity.

Finally, to interpret the CSA as foreclosing a claim of medical necessity would raise substantial doubts as to its constitutionality. Such an interpretation exceeds the limited power of Congress to regulate interstate commerce. Respondents' activities involving the private possession and use of cannabis for medicinal purposes are solely intrastate, and do not fall within Congress's power to regulate commerce or under its power to pass laws that are "necessary and proper" for such regulation.

Moreover, if the Court were to adopt the government's position, such an interpretation would deprive patients of their fundamental liberties. These fundamental liberties are secured both by the Due Process Clause of the Fifth Amendment and rights reserved to the people

and protected by the Ninth and Tenth Amendments. In this case, exercising powers reserved to them under the Tenth Amendment, the people have recognized a fundamental liberty interest in allowing access to cannabis to alleviate illness. The Court in this case can affirm and deepen its commitment to federalism, fundamental liberties, and the powers reserved to the States and the people, and by doing so enable seriously ill patients to alleviate their suffering. Or the Court can relegate these patients to the unfettered discretion of Congress without any Congressional showing that the prohibition or conduct in question is within its powers.

ARGUMENT

I. THE CSA DOES NOT DIVEST FEDERAL COURTS OF THEIR AUTHORITY TO CONSIDER EQUITABLE FACTORS, SUCH AS HARDSHIP TO SERIOUSLY ILL PATIENTS, IN FASHIONING INJUNCTIVE RELIEF.

The Court of Appeals based its ruling upon two separate and independent grounds. The court ruled that, even if the proposed injunction were coextensive with the criminal provisions of the CSA, medical necessity was a "legally cognizable defense," and the district court could modify the injunction to exempt those who qualify for this defense. Alternatively, the court concluded that in exercising its equitable discretion, the district court must balance the strong public interest in the availability of treatment that would relieve the pain and suffering of persons with serious or fatal illnesses, against the government's asserted interests. App. 8a-9a. Thus, affirmance of the ruling of the Court of Appeals does not require this Court to decide whether medical necessity is a cognizable defense in criminal prosecutions under the CSA. This Court need only reaffirm that federal courts, in the exercise of their equity jurisdiction, have discretion to modify

an injunction based upon an equitable weighing of the public interest.

When the government decided to challenge Respondents' activities, it made a conscious, tactical decision not to initiate a criminal prosecution. The government recognized that, if it initiated criminal prosecution, it would have to prove its case beyond a reasonable doubt to a twelve-member jury that could only convict upon a unanimous verdict, and it could not seek summary judgment or appeal a verdict in the defendants' favor. The government was also aware of the risk that a jury of California citizens, who overwhelmingly approve of the medicinal use of cannabis, might take a dim view of the governmental attempt to deprive grievously ill citizens of medication essential for relief during the last days of their lives. In avoiding the judgment of a jury, however, the government must submit to the discretion of a court of equity.

Any restriction of the federal courts' broad equitable discretion must plainly appear in the legislation authorizing the injunction. *Hecht Co. v. Bowles*, 321 U.S. 321, 329-30 (1944); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 329-30 (1982); *Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542-44 (1987). In conferring jurisdiction to issue injunctions against CSA violations under 21 U.S.C. § 882(a), Congress expressed no intention to limit the traditional equitable discretion of federal courts to weigh the public interest, and to consider the hardship that an injunction would impose before granting relief.

In *Hecht*, the Administrator of the Emergency Price Control Act sought an injunction barring a store from selling goods for more than the maximum price allowed under the Act. The district court refused to issue an injunction against future violations on the equitable grounds that past violations were inadvertent and the defendant had acted in good faith. As in this case, the

government argued that by giving the district court jurisdiction to issue injunctions to aid in enforcement of the Act, Congress restricted the court's traditional equitable discretion, imposing a mandatory duty to issue an injunction.

This Court ruled that district courts have broad discretion to consider equitable factors in deciding whether and how to enjoin particular conduct, even when that conduct indisputably violates an Act of Congress:

> We are dealing here with the requirements of equity practice with a background of several hundred years of history. . . . The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mold each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims.

Hecht, 321 U.S. at 329-30 n.9. Believing that an abrupt departure from this long historical tradition could not be lightly implied, this Court concluded that Congress must make its desire for such a departure plain. *Id.* at 330.

In reaching its conclusion, this Court did not consider whether "good faith" or "inadvertence" were defenses to a charge of violating the Act, focusing instead on whether there was an equitable basis for the court's decision. Similarly, the issue here is *not* whether "necessity" is a defense to violations of the CSA, but whether the district court in the exercise of its equitable discretion can appropriately consider the hardship to seriously ill individuals who have no alternative to cannabis for relief of their pain and suffering.

There is no evidence in the text of the CSA that when Congress enacted the statute in 1970, Congress intended to deprive the district courts of their traditional equitable

discretion. Indeed, Section 882(a) simply confers jurisdiction to issue injunctions.[10] Nor is there anything in the legislative history of Section 882(a) remotely suggesting that Congress intended to strip district courts of their traditional equitable discretion. *See* H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4624; S. Rep. No. 91-613, at 33 (1969).

Respondents do not dispute the government's assertion that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation," (Pet.Br. 37, 40), nor any of the cases cited to support this proposition.[11] The cases demonstrate that Congress can clearly express its intent to limit the equitable jurisdiction of the federal courts, when it wishes to do so. Congress did *not* do so in the CSA. Instead, Congress simply acknowledged the jurisdiction of the courts to issue injunctions. As recognized by this Court, however, "[a] grant of *jurisdiction* to issue compliance orders hardly suggests an absolute duty to do so under any and all circumstances." *Hecht*, 321 U.S. at 329 (emphasis added).

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[10] Section 882(a) provides:

> The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of [the CSA].

[11] *E.g., Virginian Ry. v. System Fed'n No. 40, et al.*, 300 U.S. 515, 552 (1937) (injunction mandating negotiation appropriate where Congress indicated purpose to make negotiations "obligatory"); *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 421 (1975) (inclusion of a backpay remedy in the Equal Employment Opportunity Act of 1972 was "to make possible the 'fashion[ing] [of] the most complete relief possible"); *Miller v. French*, 120 S. Ct. 2246, 2252-53 (2000) (Prison Litigation Reform Act included unambiguous limitation on equitable powers of courts to enjoin automatic stay).

This Court has not retreated from *Hecht's* insistence upon a clear expression of Congressional intent to limit equitable discretion. In *Romero-Barcelo, supra,* residents of Puerto Rico sued to enjoin the Navy from discharging waste in violation of the Federal Water Pollution Control Act (FWPCA). The district court concluded the Navy violated the FWPCA, but denied injunctive relief because the violations were "technical," there was no appreciable harm to the environment, and the Navy would be irreparably harmed if denied the opportunity to use the area. The First Circuit reversed, holding that Congress intended to impose a mandatory duty on courts to issue injunctions under the FWPCA. Reversing the First Circuit, this Court reiterated the holding of *Hecht*. 456 U.S. at 313. Moreover, as in *Hecht,* there was no discussion of whether "technicality," lack of appreciable harm to the environment, or irreparable harm to the violator are valid defenses to a prosecution under the FWPCA. *See also Village of Gambell,* 480 U.S. at 544. ("no clear indication . . . that Congress intended to deny federal district courts their traditional equitable discretion . . . nor [is this Court] compelled to infer such a limitation.")

The government relies upon *TVA v. Hill,* 437 U.S. 153 (1978), in which this Court held that in enacting the Endangered Species Act (ESA), Congress deprived district courts of discretion and mandated that injunctions issue to prevent the eradication of endangered species. Thus, the Court enjoined construction of a dam that would cause the extinction of an endangered species. *Hill* preceded *Romero-Barcelo,* which explained the *Hill* ruling in terms of the unique configuration of the ESA. The injunction in *Hill* was mandatory because it was the *only* way to fulfill the purpose of the statute. *Romero-Barcelo* 456 U.S. at 314. In contrast, in *Romero-Barcelo,* "[a]n injunction [was] not the *only means* of ensuring compliance with federal law." *Id.* (emphasis added).

Unlike the ESA considered in *Hill*, the CSA relies principally upon criminal prosecution to fulfill its prohibition of unlawful distribution of controlled substances. An injunction is *not* the *only* remedy available to fulfill its purposes. In fact, the injunction is rarely used at all. Throughout the entire thirty year history of the CSA, only two reported cases can be found in which Section 882(a) was ever employed by the government to enjoin CSA violations.[12]

The government's attempt to distinguish injunctions that "countenance" or "allow" continuing violations from those in which a court is deciding "how best to assure *compliance* with a congressional act" is disingenuous. Pet.Br. 40-42. First, the refusal to enjoin seriously ill patients from resort to the only medication that relieves their suffering is *not* to "countenance" or "allow" an alleged violation, but simply to require that the government use the alternative most commonly and routinely pursued to enforce the CSA: criminal prosecution. Second, the alleged violations that the court below held need not be enjoined did not threaten "the large objectives of the Act." *Hecht*, 321 U.S. at 331. Pet.Br. 42. The "large objective" of the CSA is to promote "the health and general welfare of the American people." 21 U.S.C. § 801(1),(2). That purpose is advanced by refusing to enjoin seriously ill Americans who have no other alternative available to stay alive, retain their sight, or stop vomiting and start eating. Third, the government overlooks the important fact that it is seeking to restrain state officers in the administration of state law, and the scope

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[12] *United States v. Leasehold Interest in 121 Nostrand Ave.*, 760 F. Supp. 1015, 1035 (E.D.N.Y. 1991) (enjoining use of public housing to facilitate narcotics offenses); *United States v. Williams*, 416 F. Supp. 611, 614 (D.D.C. 1976) (enjoining defendant from filling prescriptions).

of relief is constrained by principles of comity and federalism.[13]

Thus, the government's decision to forego criminal prosecution in this case, and seek injunctive relief for tactical reasons, does not impose a mandatory duty upon the district court and eliminate its traditional equitable discretion. The ruling of the court below recognizes the existence of that discretion, and calls upon the district court to exercise it in considering a modification of the injunction to exempt a miniscule number of seriously ill patients who face dire health consequences and have exhausted all other alternatives for relief of their suffering.

II. THE CSA DOES NOT FORECLOSE THE DEFENSE OF NECESSITY.

A. Courts Cannot Abrogate The Necessity Defense Absent a Clearly Expressed Intention by Congress to Do So.

The government argues that the CSA creates a "closed system" that forecloses any common law defense of necessity, because possession or distribution of a controlled substance in response to such necessity would not conform to the strict regulatory controls of the CSA. Pet.Br. 20-23. This extravagant claim proves too much. If the government's argument succeeded, it would foreclose not only claims of necessity, but also claims of duress and entrapment. If a defendant proved that he distributed a Schedule I substance only because someone put a gun to his head and threatened to pull the trigger, would this

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[13] "Where, as here, the exercise of authority by state officials is attacked, federal courts must be constantly mindful of the 'special delicacy of the adjustment to be preserved between federal equitable power and State administration of its own law.' [citation omitted]." *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 104 n.13 (1984).

Court declare he still committed a crime, because his act of distribution was "outside" the "closed system" of the CSA? If a defendant established that, without predisposition, he supplied a Schedule I substance to an undercover government agent who repeatedly entreated him with false claims of dire medical need, would this Court respond that a claim of entrapment was foreclosed, because the CSA does not spell out an entrapment exception to its "closed system"?

This Court has already declared that a defendant with no predisposition who is enticed into violating the CSA by a government agent *can* assert a defense of entrapment. *Hampton v. United States*, 425 U.S. 484, 490 (1976). Lower federal courts have consistently recognized that a defendant can raise a duress defense to defeat a prosecution for violating the CSA.[14] Obviously, transactions that are excused on a showing of entrapment or duress do not conform with any of the regulatory controls the CSA imposes on drug distribution, such as registration and record-keeping. Yet these defenses do not render the regulatory scheme "wholly nugatory." Pet.Br. 20, citing *United States v. Bailey*, 444 U.S. 394, 416 n.11 (1980). Rather, they make the regulatory scheme consistent with our broader notions of justice and common sense. The underlying purpose of the CSA is not the bureaucratic compilation of a paper trail for every transfer of a pill but rather to promote "the health and general welfare of the American people." 21 U.S.C. § 801(1),(2). The minuscule number of transactions that would be excused by a necessity defense, where the necessity is to avoid greater

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[14] *See, e.g., United States v. Contento-Pachon*, 723 F.2d 691 (9th Cir. 1984). The duress defense sometimes has been rejected under the CSA not because the CSA does not allow the defense, but because the defendant did not present credible evidence that other alternatives were not available. *See, e.g., United States v. Posada-Rios*, 158 F.3d 832 (5th Cir. 1998), *cert. denied*, 526 U.S. 1031 (1999).

harms such as death, blindness, or starvation, would not render the registration or record-keeping regulations of the CSA "wholly nugatory."

In terms of the underlying common law policies that justify them, the defenses of duress and entrapment are indistinguishable from the necessity defense. In *Sorrells v. United States*, 287 U.S. 435 (1932), this Court addressed the availability of the entrapment defense to a charge of distributing whiskey in violation of the "closed system" created by the National Prohibition Act. The government made essentially the same argument it makes here: "the legislature, acting within its constitutional authority, is the arbiter of public policy and that, where conduct is expressly forbidden and penalized by a valid statute, the courts are not at liberty to disregard the law and to bar a prosecution for its violation because they are of the opinion that the crime has been instigated by government officials." *Id.* at 445-46. In rejecting this argument, Chief Justice Hughes turned to the venerable precedent of *Kirby*, where the Court declared:

> All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language, which would avoid results of this character.

7 Wall. at 486-87. Among its "common sense" illustrations of this principle, the Court cited the common law ruling that a statutory prohibition of prison escape "does not extend to a prisoner who breaks out when the prison is on fire – 'for he is not to be hanged because he would not stay to be burnt.' " *Id.* at 487.

In similar terms, and again citing *Kirby*, this Court recognized that a defense of duress or necessity could be asserted to a violation of the Congressional prohibition of prison escape, 18 U.S.C. § 751(a):

> The statute itself, as we have noted, requires no heightened *mens rea* that might be negated by any defense of duress or coercion. We nonetheless recognize that Congress in enacting criminal statutes legislates against a background of Anglo-Saxon common law, see *Morissette v. United States*, 342 U.S. 246 (1952), and that therefore a defense of duress or coercion may well have been contemplated by Congress when it enacted § 751(a).

Bailey, 444 U.S. at 415-16 n.11.

Necessity is among the oldest and most deeply entrenched defenses in Anglo-Saxon common law, whose roots can be traced to the mid-thirteenth century in England, and earlier on the Continent.[15] Although the necessity defense is frequently analyzed in consequentialist terms, calling for a utilitarian "balancing" of the "harms," it also implicates a moral judgment by a jury regarding the defendant's conduct.[16] The crucial role of the jury, in turn, suggests that courts should approach with caution the argument that a legislature has foreclosed a necessity defense by making its own balance of competing values. A legislative judgment cannot accommodate all of the factual variables that might affect a moral judgment of what is right and proper under the circumstances.

Similarly, the Model Penal Code, in its formulation of the necessity defense, suggests caution in concluding the

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[15] *See* Reeve, *Necessity: The Right to Present a Recognized Defense*, 21 New Eng. L. Rev. 779, 781-84 (1986); Conde, *Necessity Defined: A New Role in the Criminal Defense System*, 29 U.C.L.A. L. Rev. 409 (1981); Arnolds & Garland, *The Defense of Necessity in Criminal Law: The Right to Choose the Lesser Evil*, 65 J. Crim. L. & Criminology 289 (1974).

[16] *See* Fletcher, *Rethinking Criminal Law*, § 0.2 at 792-93 (1978); Hall, *General Principles of Criminal Law*, p. 419 & n.16 (2d Ed. 1960); Parry, *The Virtue of Necessity: Reshaping Culpability and the Rule of Law*, 36 Houston L. Rev. 397 (1999).

defense is legislatively foreclosed in its requirement that a legislative purpose to exclude the justification "plainly appear." Model Penal Code, § 3.02(1)(c) (1962).[17] Congress has never enacted a statute that explicitly foreclosed the common law defenses of necessity, duress, or entrapment, and this Court has never found that abrogation of any of these defenses could be implied from the language of any Congressional enactment.

The record in this case offers some dramatic examples of the compelling dimensions of necessity claims. Consider, for example, the plight of Robert Bonardi, the 74-year-old owner of a vacuum cleaner store who is now deceased. J.A. 80. Mr. Bonardi survived a bout of cancer of the larynx with a permanent tracheotomy, and lived through prostrate cancer. With the discovery of numerous new tumors in his neck and chest, he underwent an aggressive regimen of radiation and chemotherapy. He experienced serious nausea as a side effect of the chemotherapy:

> I would retch whenever I thought about food or whenever anyone tried to put food in front of me. The nausea made me particularly afraid to eat because my throat condition makes it especially unpleasant if I vomit. Not only would vomit come out of my mouth, but it would also come out of my nose.

J.A. 81. After losing forty pounds in six weeks, and finding none of the prescribed medications helped, Mr. Bonardi's daughter brought him to the Cooperative. "At first I did not want to go," he said. "It took my daughter a long time to convince me to go. I am 74 years old, and

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[17] Even Professor LaFave, a leading proponent of the utilitarian approach, emphasizes that courts must be free to consider the merits of a necessity claim when a statute is silent upon the matter. Wayne LaFave, *Criminal Law*, § 5.4 at p. 478 (3d Ed. 2000).

had never used marijuana before in my life." After struggling to consume a cannabis brownie (he could not smoke), he reported:

> [F]or the first time in several weeks, I felt like eating. The brownie caused my nausea to go away. I asked my wife to cook me eggs and sausage. She was so happy because it had been so long since I had asked for food. I have since regained some of the weight I lost.

J.A. 82. If Mr. Bonardi were our own father or brother, which of us would hesitate for a moment before supplying him with cannabis? Would any civilized society *punish* Mr. Bonardi or his daughter? Under circumstances such as these, implicating the very instinct for survival, the necessity defense simply reflects the law of nature:

> This law of nature, being coeval with mankind and dictated by God himself, is of course superior in obligation to any other. It is binding over all the globe in all countries, and at all times; no human laws are of any validity, if contrary to this; and such of them as are valid derive all their force, and all their authority, mediately or immediately, from this original.

1 William Blackstone, *Commentaries* *39.

The government cannot seriously suggest that Congress intended to foreclose all claims of necessity when it enacted the CSA, and made a conscious value choice that the majesty of the federal law outweighed the retching discomfort of patients such as Robert Bonardi. The common law defense of necessity wisely allows the assessment of the moral culpability of Mr. Bonardi and his daughter to rest in the hands and hearts of an American jury.[18]

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[18] A common law necessity defense may be asserted by both the patient and the person who provides the medication

B. Recognition of a Defense of Necessity Is Not Inconsistent with the Congressional Classification of Marijuana on Schedule I of the CSA.

Unable to point to any explicit rejection of any common law defenses in the text of the CSA, the government erroneously asserts that Congress "has declared" and "found" that marijuana has no "currently accepted medical use in treatment in the United States," and has no "accepted safety for use * * * under medical supervision," citing the criteria contained in 21 U.S.C. § 812(b)(1)(B) and (C). Pet.Br. 13, 20. Section 812(b), however, implies no Congressional finding or declaration about cannabis whatsoever. Section 812(b) merely establishes the criteria for *administrative* classification or reclassification of drugs pursuant to 21 U.S.C. § 811. When *Congress* directly classifies a drug, as it did cannabis in 1970, it is not bound by the criteria in section 812(b). In fact, Congress has directly classified drugs on Schedule I precisely because they *did* have an accepted medical use, and for that very reason they could not be *administratively* placed on Schedule I.[19]

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needed to avoid imminent harm. *United States v. Newcomb*, 6 F.3d 1129 (6th Cir. 1993) ("it is fundamental that the defense must apply equally to a choice-of-evils case when the evil is to a third party as to the case where the evil is to one's self").

[19] In 1984, Congress by statute ordered the transfer of methaqualone from Schedule II to Schedule I of the CSA, even though it was universally acknowledged to have an accepted medical use and had been approved for marketing by the FDA. Pub. L. 98-329, 98 Stat. 280 (1984). The House Committee Report noted:

> [T]he [DEA] does not have authority to impose Schedule I controls on a drug which has been approved by the [FDA] for medical use. The statutory findings required for agency scheduling decisions clearly state that the agency may not, *in the absence of Congressional action*, subject drugs with a currently

Thus, mere placement of a substance on Schedule I *by Congress* implicates no declaration, finding, or any determination whatsoever as to its currently accepted medical use. It only indicates Congress wishes to assert the most restrictive level of controls created by the CSA over its use. The assertion of the most restrictive level of controls over a substance, in turn, implies no judgment regarding the availability of a defense of necessity to justify use in exceptional, urgent circumstances.

Alternatively, the government suggests that a court cannot reconcile the common law doctrine of necessity with the statutory procedures for administrative reclassification of drugs. Respondents do not challenge the current classification of cannabis in these proceedings.[20] Administrative reclassification is a process that addresses the availability of drugs for general medical use, not the appropriateness of its use by an individual patient who has no other alternative to avoid imminent harm. In the context of administrative reclassification, the statutory criteria of "currently accepted medical use" serves a completely different purpose than the necessity defense. In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994), the court upheld a five-part test formulated by the DEA to determine whether a drug is in "currently accepted medical use":

> (1) The drug's chemistry must be known and reproducible;
>
> (2) There must be adequate safety studies;

> accepted medical use in the United States to Schedule I controls.

H.R. Rep. No. 98-534, 98th Congress, 2d Sess. 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 540, 543-44 (emphasis added).

[20] Nor do Respondents seek permission to market cannabis as a "new" drug in interstate commerce. Thus, the restrictions of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, (*see* Pet.Br. 6) are irrelevant.

> (3) There must be adequate and well-controlled studies proving efficacy;
> (4) The drug must be accepted by qualified experts;
> (5) The scientific evidence must be widely available.

Id. at 1135, citing 57 Fed. Reg. at 10,506. If cannabis meets these criteria, the DEA can administratively reclassify it to another schedule of the CSA and it will then be generally available by prescription from any physician. The physician will not then be required to treat a patient who must meet the stringent criteria for medical necessity. *See* App. 16a-17a. But it is unreasonable to expect a patient who demonstrates true legal necessity to await the drug's administrative reclassification. As the district court noted, the last challenge to the Schedule I classification of cannabis took over twenty years to resolve. "Needless to say, it hardly seems reasonable to require an AIDS, glaucoma, or cancer patient to wait twenty years if the patient requires marijuana to relieve a current medical problem." App. 70a. The necessity defense exists to accommodate the urgent needs of a particular patient who will suffer a greater harm if denied access to the drug. The necessity doctrine functions as a safety valve, to prevent rigid application of the law despite unusual circumstances the legislature did not contemplate.

Viewed from this perspective, the concept of necessity reflects the reality of medical practice. A physician can freely resort to the generally accepted pharmacopoeia in the general treatment of patients. But when all generally accepted treatments prove ineffective or intolerable, the physician and the patient may jointly agree that necessity requires treatment that has not yet achieved general acceptance. The necessity doctrine applies to a particular patient or class of patients who have exhausted all generally accepted treatments. The CSA is not at war with good medical practice, and good medical practice requires that physicians keep searching, even when conventional, generally accepted remedies do not work.

C. Nothing in the Legislative History of the CSA Suggests Any Intent to Abrogate the Common Law Necessity Defense.

Congress conceded that it lacked information to make any judgment about medical necessity for cannabis when it enacted the CSA in 1970. Months before it enacted the CSA, Congress enacted the Marijuana and Health Reporting Act, Pub. L. No. 91-296, § 501-03, 1970 U.S.C.C.A.N. 418, which directed the Secretary of HEW to prepare a report within 90 days and annually thereafter, "containing current information on the health consequences of using marihuana" and "containing such recommendations for legislative and administrative action as he may deem appropriate." *Id.* Congress ordered this report because it had found that "notwithstanding the various studies carried out, and research engaged in, with respect to the use of marihuana, there is lack of an authoritative source for obtaining information involving the health consequences of using marihuana." *Id.*

On August 14, 1970, during the debates on the CSA but before the report was to be completed, HEW advised Congress as follows:

> Some question has been raised whether the use of the plant itself produces "severe psychological or physical dependence" as required by Schedule I or even a Schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marijuana be retained within schedule I at least until the completion of certain studies now underway to resolve this issue.

H.R. Rep. No. 91-1444 (1970) *reprinted in* 1970 U.S.C.C.A.N. at 4579 & 4629. Congress tentatively placed marijuana on Schedule I, but to resolve uncertainty, created the bipartisan Commission on Marihuana and Drug Abuse (the "Shafer Commission"), and directed it to prepare a report to guide Congress. *Id.; see* Act of Oct. 27, 1970, Pub. L. No. 91-513, § 601, 1970 U.S.C.C.A.N. (84 Stat.) 1489-90. The report was to

include a study of "the pharmacology of marihuana and its immediate and long-term effects, both physiological and psychological" as part of a "comprehensive report" that included proposals for legislation and administrative action as may be necessary to carry out its recommendations. Act of Oct. 27, 1970, Pub. L. 91-513, § 601(d)(1)(C) & (2), 1970 U.S.C.C.A.N. (84 Stat.) 1490.

The Shafer Commission recommended that Congress amend the CSA, and that the States amend their laws, so that all possession of marijuana for personal use would not subject the possessor to punishment, even as a misdemeanor, and "casual distribution of small amounts of marihuana for no remuneration, or insignificant remuneration not involving profit would no longer be an offense." *Marijuana: A Signal of Misunderstanding; First Report of the National Commission on Marihuana and Drug Abuse*, 152-53 (1972). Thus, the legislative history of the treatment of cannabis yields neither an explicit rejection of a necessity defense, nor any implicit criticism of such a defense.

Because the CSA is a criminal statute, which imposes severe penalties for its violation, courts must interpret it using the "ancient rule of statutory construction that penal statutes should be strictly construed against the government . . . and in favor of the persons on whom the penalties are sought to be imposed." 3 Sutherland Stat. Const. § 59.03, p. 102 (5th Ed. 1992). A corollary to this ancient rule is that when, as in this case, the "text, structure, and history fail to establish that the Government's position is unambiguously correct – [courts] apply the rule of lenity and resolve the ambiguity in [the defendant's] favor." *United States v. Granderson*, 511 U.S. 39, 54 (1994). Drug laws are no exception to this rule, as this Court warned in *Granderson*. The government cannot rely on general statements that Congress intended to "get tough on drug offenders," but must point to specific evidence that Congress expressed intent on the narrow issue in question. *Id.* at 49.

Acceptance of the government's argument in this case would make the CSA the only federal criminal prohibition to which a citizen could not assert a necessity defense. However, citizens are entitled to clear notice if a particular criminal statute proscribes more conduct than the criminal laws generally proscribe. *See, e.g., Crandon v. United States*, 494 U.S. 152, 158 (1990) (The rule of lenity is a " 'time-honored interpretive guideline' [that] serves to ensure both that there is fair warning of the boundaries of criminal conduct and that legislatures, not courts, define criminal liability.").

If a court were to construe the CSA to impose broader criminal liability than any other statute enacted by Congress, the government must point to its text to support such a construction. If the text is silent or ambiguous, a finding of Congressional intent to abrogate a universally available defense should not be based on the statute's legislative history.[21] In this case, nothing in the CSA's legislative history evidences any intent to abrogate the necessity defense.

D. Government Acquiescence in the Continued Governmental Distribution of Cannabis to Patients Demonstrating Necessity Confirms that a Necessity Defense Is Not Inconsistent With the CSA.

Throughout the thirty years that federal authorities have administered the CSA, they have perceived no inconsistency between the classification of marijuana on Schedule I, and the federal program for therapeutic use by patients whose serious medical conditions could be alleviated only by the use of cannabis. Federal authorities continue to supply these patients with government-grown cannabis to this very day. At last report, there are eight patients still enrolled in this

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[21] "Because construction of a criminal statute must be guided by the need for fair warning, it is rare that legislative history or statutory policies will support a construction of a statute broader than that clearly warranted by the text." *Crandon*, 494 U.S. at 160.

program who receive a regular supply of medical cannabis from the United States government. *Despite Marijuana Furor, 8 Users Get Drug From The Government,* The N.Y. Times, Dec. 1, 1996, p. 33.

The government initiated the Compassionate Investigative New Drug ("I.N.D.") program to settle a lawsuit filed by glaucoma patient Robert Randall after he was acquitted of unlawful cannabis cultivation in the District of Columbia, based upon a showing of necessity. *United States v. Randall,* 104 Wash. D. Rep. 2249 (D.C. Super., 1976).[22]

Randall presented incontrovertible evidence that use of cannabis dramatically reduced the intraocular eye pressure caused by his glaucoma with greater success than conventional medical treatment. Sustained high intraocular pressure causes permanent nerve damage and eventual blindness. The court ruled, "'The evil he sought to prevent, blindness, is greater than that he performed to accomplish it, growing marijuana in his residence in violation of the D.C. Code." *Id.* at 2252-53.

In response to Randall's dilemma, the federal government created an I.N.D. protocol to make government-grown cannabis available for medical treatment.[23] By 1983,

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[22] *See also* Robin Isenberg, *Medical Necessity As a Defense to Criminal Liability: United States v. Randall,* 46 Geo. Wash. L. Rev. 273 (1978).

[23] In testimony before the House Select Committee on Narcotics Abuse and Control in 1980, Randall congratulated the National Institute on Drug Abuse, the Federal Drug Administration, and the Drug Enforcement Administration for devising a plan to meet his medical necessity:

> My private physician writes prescriptions, and I take these prescriptions to a pharmacy near my home here in Washington, D.C. On the basis of such a prescription, the pharmacy provides me with seventy NIDA prepared and pre-rolled marijuana cigarettes

the FDA had approved seventy-nine I.N.D. plans to permit therapeutic use of THC and cannabis. These plans dealt with nausea and vomiting from cancer chemotherapy, glaucoma, spasticity, and weight loss.[24] Jones & Lovinger, *The Marijuana Question*, 136 (1985). These were *not* clinical trials to test the drug for eventual approval, however. Rather, they were a convenient umbrella for the government to administer a program of medical use by patients demonstrating necessity:

> The very existence of the compassionate-care program contradicts federal policy and puts the Food and Drug Administration in an "awkward position," said Don McLearn, a spokesman for the Agency. Despite its name, the Compassionate Investigative New Drug program, known as a compassionate I.N.D., is not a research study intended to evaluate the medicinal value of marijuana. "It is not a clinical trial," Mr. McLearn said, "There was never any intent of using reports from the compassionate I.N.D.'s to reach approval for the drug."

> of a known potency. Dismissing all past complaints, NIDA, FDA, and DEA have been, are now, and will continue to provide me with marijuana within a system of care which respects my personal needs and reflects the medical demands of my condition, not the preordained assumptions of a federal bureaucrat.

Therapeutic Uses of Marijuana and Schedule I Drugs, Hearing Before the Select Committee on Narcotics Abuse and Control, House of Representatives, 96th Cong., 2d Sess., May 20, 1980, at p. 8.

[24] In *United States v. Burton*, 894 F.2d 188 (6th Cir. 1990), when a glaucoma patient asserted a necessity defense in federal court, the defense was rejected *not* because it was inconsistent with the classification of marijuana on Schedule I; but because the Compassionate I.N.D. program at that time provided a reasonable legal alternative to violating the law. 894 F.2d at 191.

Despite Marijuana Furor, 8 Users Get Drug From the Government, The N.Y. Times, Dec. 1, 1996, p. 33.

The consistent interpretation of the CSA by those charged with its administration to permit medical use by some patients with necessity is persuasive evidence that the Schedule I classification was *never* intended to preclude any use for medical purposes.[25] It should be presumed that legislative intent has been correctly discerned when an agency's interpretation has been fully brought to the attention of the public and Congress, and the latter has not sought to alter that interpretation. *United States v. Rutherford*, 442 U.S. 544, 554 n.10 (1979).[26]

The government still operates the Compassionate I.N.D. Program for eight patients. The government cannot reconcile its establishment and continued administration of the Compassionate I.N.D. program providing cannabis to seriously ill patients with its argument in this case that the operation of a local government's compassionate program providing cannabis to seriously ill patients under circumstances demonstrating necessity violates federal law. The placement of cannabis on Schedule I of the CSA is not inconsistent with either program. Both are fully justified by necessity.

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[25] *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (The rulings, practices, and opinions of administrators "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.").

[26] Congress was made fully aware of the operation of the Compassionate I.N.D. Program to meet the medical needs of select patients. *See* Therapeutic Uses of Marijuana and Schedule I Drugs, Hearing Before the Select Committee on Narcotics Abuse and Control, *supra* n.23. Testimony of Dr. Marvin Snyder, National Institute on Drug Abuse. *Id.* at 821. The program was also widely publicized in press and television reports. Randall & O'Leary, *Marijuana Rx: The Patient's Fight for Medicinal Pot* (1998).

E. The Widespread Creation of "Therapeutic Research Programs" by States That Have Adopted the Uniform Controlled Substances Act Demonstrates that Accommodation of Necessity Is Not Inconsistent With the CSA.

The CSA served as the model for the Uniform Controlled Substances Act (the "Uniform Act"), subsequently adopted by forty-eight states.[27] The Uniform Act establishes the same five schedules as the federal act, with the same criteria to determine which drugs are placed on which schedule. Just as under the CSA, the Uniform Act places marijuana on Schedule I.[28] Of the forty-five states that maintain the classification of marijuana on Schedule I, twenty-six subsequently enacted the "Controlled Substances Therapeutic Research Act," (TRA) recognizing the therapeutic value of cannabis and permitting its use for medical purposes in circumstances virtually identical to the circumstances presented in cases of necessity: patients suffering from life-threatening or sight-threatening illnesses for whom the alternatives offered by conventional medicine do not work. *See Marijuana, Medicine & The Law* (Randall, Ed.) at 279 (1987).

The most important aspect of this history is the fact that so many states were willing to accommodate the urgent medical needs of patients for cannabis, even

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[27] Only New Hampshire and Vermont failed to enact the Uniform Controlled Substances Act. *See* Table, Uniform Controlled Substances Act, 21 U.S.C.A. § 357 to 840, pp. 539-40 (West 1999); Unif. Controlled Substances Act, 9 U.L.A., Part II, pp. 1-2 (1997).

[28] Most states adopting the Uniform Act retained its classification of marijuana on Schedule I. *But see* Alaska Statutes, § 11.71.160 (Michie 2000) (Schedule IIIA); Ark. Code Ann. § 5-64-215 (Schedule VI) (Michie 1999); D.C. Code Ann. § 33-516 (Schedule II) (1981); 17-A Maine R.S. § 1102 (1999) (Schedule Z); N.C. Gen. Stat. § 90-94 (2000) (Schedule 6); Tenn. Code Ann. § 39-17-408, 415 (2000) (Schedules 2, 4).

though they classified it on Schedule I of their Controlled Substances Act. They saw no inconsistency between a Schedule I classification and a finding that access to the drug was necessary for patients facing potential loss of life or sight.

Although interpretations of state statutes do not control construction of federal law, they can indicate general understanding of terms such as "no currently accepted medical use." *Cf. Espinoza v. Farah Mfg. Co., Inc.*, 414 U.S. 86, 88 n.2 (1973). This is especially true where the state and federal statutes employ precisely the same language.

The government cites the rejection of a necessity defense by the Supreme Court of New Jersey as a purported example of the principle that the necessity defense is unavailable when the legislature has foreseen the circumstances faced by the defendant and rejected them. *State v. Tate*, 505 A.2d 941, 946 (1986); Pet.Br. 18 n.9. This ignores the fact, however, that New Jersey is among the states that adopted the TRA. The *Tate* court rejected a statutory defense of necessity based upon its satisfaction "that our legislature has contemplated the defense urged by Michael Tate, has provided a specific exception dealing with it (citing the TRA) and has made plain its intent to exclude the defense as specifically provided." 505 A.2d at 945. Thus, the legislative "rejection" suggested by the government was actually the adoption of the necessity exception in the TRA, which Michael Tate did not utilize. The New Jersey Court concluded that even if cannabis were not available for medical purposes through the state's TRA, "marijuana is and was legally available through the FDA," noting that eight of the 79 patients then enrolled in the federal Compassionate I.N.D. program were also afflicted with spasticity. *Id.* at 946 n.1.

Thus, there is widespread concurrence among the states adopting the Uniform Act that the classification of cannabis on Schedule I is not inconsistent with permitting the medical use of cannabis under circumstances closely

analogous to the necessity defense, or even with the explicit recognition of a necessity defense. This strongly supports the conclusion that parallel provisions in the CSA do not prohibit recognition of the necessity defense in federal cases.

F. The 1998 "Sense of Congress" Resolution Does Not Restrict the Availability of a Necessity Defense Under the CSA.

Lacking any credible support in the text or legislative history of the CSA to suggest foreclosure of a necessity defense, the government seizes upon a "Sense of Congress" resolution that Schedule I drugs "are unsafe, even under medical supervision." Pet.Br. 7-8, quoting Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760. This is not a finding of fact based upon any hearings or empirical investigation meriting judicial deference. In truth, it is not a finding of fact at all. It is buried in the massive *Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999*.[29]

Though captioned, "Not Legalizing Marijuana for Medical Use," the resolution contains no findings concerning the medical use of cannabis or anything else. It merely reiterates provisions of the CSA and Federal Food, Drug, and Cosmetic Act, and expresses opposition to efforts to "legalize" marijuana for medical use. Neither the court below nor the district court purported to "legalize" marijuana, however. They merely declined to enjoin its use under limited circumstances where the patient will suffer

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[29] The Sense of Congress resolution did not purport to amend the CSA, nor could it do so by implication. Repeals by implication are especially disfavored in the appropriations context. *Hill*, 437 U.S. at 190-191. Congress may amend substantive law in an appropriations statute, but only if it clearly expresses its intent to do so. *Robertson v. Seattle Audubon Soc'y*, 503 U.S. 429, 440 (1992).

imminent harm and all available alternatives are ineffective or intolerable.

The "Sense of Congress" resolution makes no mention of necessity. The statements of the sponsor quoted in the government's brief (Pet.Br. 26) confirm that his purpose was to express opposition to the enactment of initiative measures by the States, which permit much broader use of cannabis for medical purposes than does the doctrine of medical necessity. A Congressional resolution expressing political opposition to state initiatives does not have the force of law. *Boos v. Barry*, 485 U.S. 312, 327-28 (1988).

Characterizing the resolution as reinforcement of a previous prohibition of unauthorized distribution of marijuana (Pet.Br. 26 n.15) simply engages us in tautology. While the classification of marijuana on Schedule I precludes the issuance of ordinary medical prescriptions, it does not purport to preclude its use under circumstances of necessity. The CSA is silent as to the defense of necessity – and the "Sense of Congress" resolution adds nothing to that silence.

G. *United States v. Rutherford* Does Not Support the Government's Contention that Necessity Is Not Available As a Defense Under the CSA.

Citing this Court's holding in *United States v. Rutherford*, 442 U.S. 544 (1979), the government argues that a claim of "medical need" cannot override a Congressional judgment. Pet.Br. 27. Here, of course, Respondents do not contend that their medical need "overrides" Congressional intent, but that Congress has expressed no intent to limit the availability of common law defenses such as necessity under the CSA. The claim made in *Rutherford* was very different: that drugs used by the terminally ill were an implied exception to the safety and effectiveness standards imposed by the FDA upon the interstate marketing of new drugs.

Here, the government seeks to enjoin seriously ill patients from individually obtaining a therapy of proven

effectiveness and which is their only available alternative. In *Rutherford*, a group of patients sought to enjoin the government from interfering with the interstate shipment and sale of Laetrile. No claim of "necessity" was asserted, nor could one be asserted.[30] There was no credible evidence to support the claim that Laetrile was a cancer cure. The *Rutherford* plaintiffs asserted a right to use it *regardless* of its efficacy, simply because they were terminally ill. The Court responded that Congress clearly intended the protections of the Food, Drug, and Cosmetic Act to apply to the terminally ill, to protect them from fraudulent cures whose false claims might induce them to forego conventional treatment.[31] 442 U.S. at 552-53.

The Court also noted that the FDA itself had never made exception for drugs used by the terminally ill. *Id.* at 553. The FDA has, on the other hand, made exceptions for the medical use of cannabis through the Compassionate I.N.D. Program.

Rutherford does not support the government's position in this case. The ruling this Court reversed in that case would have "den[ied] the Commissioner's authority over all drugs, however toxic or ineffectual, for [terminal patients]." *Id.* at 557-58. In contrast, the Court of Appeals' decision here does not challenge to the authority of Congress or the DEA to classify or reclassify substances under

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[30] The only case in which a claim of "medical necessity" for Laetrile was ever asserted is *United States v. Richardson*, 588 F.2d 1235 (9th Cir. 1978). Defendants were convicted of illegally smuggling Laetrile from Mexico. The defense was rejected, not because the statute precluded it, but because the defendants could not establish that no reasonable alternatives to violation of the law were available. *Id.* at 1239.

[31] There is no risk that patients who use cannabis as a medicine will forego conventional treatment. Cannabis is used to alleviate symptoms, or side-effects of conventional treatments. In this respect, it actually *promotes* the conventional treatment. J.A. 127-129.

the CSA, nor does it limit the government's power to enforce the CSA. Rather, the decision merely protects individual patients' access to a medication that has been shown to offer the only source of relief for their torment.

III. IF THE CSA IS INTERPRETED TO FORECLOSE A NECESSITY DEFENSE, IT IS UNCONSTITUTIONAL.

Courts must interpret all statutes, including the CSA, to avoid constitutional problems, so long as the saving construction is not "plainly contrary to the intent of Congress." *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 78 (1994), *Solid Waste v. United States*, 2001 WL 15333 (U.S. Jan. 7, 2001) (interpreting Clean Water Act narrowly to avoid "significant constitutional and federalism questions" under *United States v. Lopez*, 514 U.S. 549 (1995) and *United States v. Morrison*, 120 S. Ct. 1740 (2000)). If the Court accepts the government's argument that the CSA abrogated the discretion of federal courts to balance the potential harm to patients in issuing injunctions, and eliminated the medical necessity defense even for seriously ill patients with no other alternative, the Court must decide whether Congress exceeded the powers granted to it by the Constitution to regulate interstate commerce, violated the substantive due process rights of patients to be free from pain and preserve their lives and infringed upon rights expressly retained by the people of California and powers reserved by the people and State of California in violation of the Ninth and Tenth Amendments.

A. It Is Beyond The Powers of Congress Under Either the Commerce Clause or The Necessary and Proper Clause to Prohibit the Use of Cannabis In Cases of Medical Necessity.

The government seeks to prohibit the medical use of cannabis by seriously ill persons upon recommendation of their physicians, and the cultivation and distribution of

cannabis for this limited purpose by an organization authorized and regulated by a local municipality in accordance with state law. If this prohibition exceeds the enumerated powers of Congress, there is no need to consider whether the prohibition violates a fundamental right.

Congress has no general police powers. *Lopez*, 514 U.S. at 566 ("The Constitution . . . withhold[s] from Congress a plenary police power that would authorize enactment of every type of legislation."); *McCulloch v. Maryland*, 17 U.S. (4 Wheat) 316, 405 (1819); *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 176 (1803) ("The powers of the legislature are defined, and limited; and that those limits may not be mistaken or forgotten, the constitution is written."). The Constitution confines Congress to enumerated powers and execution of those powers through laws that are necessary and proper.

The activities involved in this case fall within neither the power of Congress "to regulate Commerce . . . among the several states," nor its power to pass laws that "shall be necessary and proper" to execute its power to regulate commerce. U.S. Const., Art. I, § 8. The private possession, use, and cultivation of cannabis for medicinal purposes is not commerce at all. While the buying or selling of cannabis may be commerce, the prohibition asserted by the government here extends to *any* distribution, even the delivery from a primary caregiver to the patient for no charge.

As recently noted by this Court, "thus far in our Nation's history our cases have upheld Commerce Clause regulation of intrastate activity only where that activity is economic in nature." *Morrison*, 120 S. Ct. at 1751; *see also id.* at 1750 ("[W]here we have sustained federal regulation of intrastate activity based upon the activity's substantial effect on interstate commerce, the activity in question has been some sort of economic endeavor."). Supplying cannabis to another for medical purposes without charge is not an economic endeavor. Nor is growing a cannabis

plant for one's own medical use. Therefore, like the crime of rape in *Morrison*, the regulation and prohibition of these activities lie solely *within the police power of the state*. The fact that the possession, use and cultivation of cannabis for medical purposes is a nonviolent activity related to health only bolsters this conclusion. *See GMC v. Tracy*, 519 U.S. 278, 306 (1997) (reaffirming the paramount interest of the states in regulating health matters.)[32]

Only the cultivation and distribution of cannabis in exchange for money or barter can be considered commerce, but even such commerce here is exclusively intrastate and therefore not within the power of Congress to regulate commerce "among the states." The government does not dispute that Respondents provided cannabis grown entirely in California, by California cultivators, and distributed wholly within California, by only California residents, exclusively to California patients, who had recommendations or approvals issued solely by California-licensed physicians, for use only within California.[33]

If Congress is to reach the solely intrastate distribution of cannabis for medical use, it must do so under its power to pass laws that are "necessary and proper" to put

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[32] Nor can the noncommercial possession, use or cultivation of cannabis for medicinal purposes be reached under the "aggregation principle" of *Wickard v. Filburn*, 317 U.S. 111 (1942). As was explained in *Morrison*, "in every case where we have sustained federal regulation under *Wickard's* aggregation principle, the regulated activity was of an apparent commercial character." *Morrison*, 120 S. Ct. at 1750 n.4. These activities are neither economic nor commercial and are therefore outside the power of Congress either under the Commerce Clause or the expansive reading of the Necessary and Proper Clause adopted in *Wickard*.

[33] Should there be any doubt about the reach of the medical necessity exception to the injunction below, this Court can remand the case to clarify that it applies only to exclusively intrastate cultivation and distribution.

into execution its enumerated powers. *See New York v. United States*, 505 U.S. 144, 158 (1992) ("The Court's broad construction of Congress' power under the Commerce and Spending Clauses has of course been guided, as it has with respect to Congress' power generally, by the Constitution's Necessary and Proper Clause. . . . ").

In *Morrison* and *United States v. Lopez*, 514 U.S. 549 (1995), this Court recognized previous rulings that Congress may reach wholly intrastate *economic* activity under the Necessary and Proper Clause if that activity was shown to "substantially affect interstate commerce." *Lopez*, 514 U.S. at 560 (emphasis added). Here, however, as in *Lopez*, the government has not shown that the wholly intrastate distribution of cannabis solely for medical use would have a "substantial effect" on interstate commerce.[34] As with the statute at issue in *Lopez*, neither the CSA "nor its legislative history contain express Congressional findings regarding the effects upon interstate commerce" (*id.* at 562) of the wholly intrastate use and distribution of cannabis for medical use. The findings in the CSA regarding jurisdiction over intrastate activity are general, and do not address in any manner the effect of recognizing a defense of medical necessity upon interstate commerce. *See, e.g.*, 21 U.S.C. § 801(4) ("Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances."); 21 U.S.C. § 801(5) ("Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate.").

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[34] This case is thus distinguishable from lower court cases generally upholding the constitutionality of the CSA as applied to illicit intrastate drug trafficking. *See, e.g., United States v. Tisor*, 96 F.3d 370 (9th Cir. 1996).

Neither of these findings addresses the standard articulated in *Lopez* and *Morrison:* whether the intrastate production or distribution of cannabis for medical purposes has a *substantial effect* upon interstate commerce. Interpreting the Necessary and Proper Clause to allow Congress to prohibit the wholly intrastate commerce of a particular good on the unsupported speculation that such goods might "contribute to swelling" interstate commerce, or because the goods produced within a state "cannot be differentiated" from those imported from other states, would give Congress the plenary power over all commerce that the Constitutional text explicitly denies it. If this satisfies the standard of *Lopez* and *Morrison*, then Congress could render these two decisions inoperative simply by accompanying every prohibition of intrastate economic activity with a blanket assertion that the activity "substantially affects interstate commerce."[35]

Moreover, under the medical necessity standard articulated by the courts below, a qualified patient must, by definition, meet an extremely strict four-prong test. App. 16a-17a. To meet the requirement of *Lopez* (and *Wickard*), the government must show that permitting *this* very limited activity would, in the aggregate, have a substantial effect on commerce between the states, something it has not even attempted to do.

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[35] In *Wickard v. Filburn, supra,* the Court found that Congress could regulate the intrastate production and consumption of wheat because such production and consumption was in competition with wheat sold interstate, and therefore only by reaching these intrastate activities could it successfully increase the market price of wheat in interstate commerce. *See Lopez,* 514 U.S. at 560, quoting *Wickard.* Here, there is no federal scheme of price maintenance with which the intrastate production of medical cannabis could possibly interfere. Rather, the CSA is a scheme to prohibit completely all commerce in cannabis.

B. The Government's Interpretation Violates the Substantive Due Process Rights of Patients.

Even if the Court finds the CSA as applied to medical necessity patients is within the power of Congress, such an application would violate the patients' fundamental rights. This Court has established that the Due Process Clause "provides heightened protection against government interference with certain fundamental rights and liberty interests". *Washington v. Glucksberg*, 521 U.S. 702, 719 (1997) (citations omitted).[36] Declarations from many of the patients served by Respondents establish that access to medical cannabis is the reason they are alive today. J.A. 42, 44-45, 82, 84-85, 89. These patients have a liberty interest in being free from pain and in preserving their lives with assistance of a physician.[37] *See Glucksberg*, 521 U.S. at 737, 745 (O'Conner, J., concurring) (Stevens, J., concurring) ("Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly '[a]t the heart of [the] liberty . . . to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life.' "). More precisely, these

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[36] In *Queen v. Parker*, No. C28732L (Ont. App. July 31, 2000) the Ontario Court of Appeal upheld a constitutional challenge by an epileptic to the prohibition against the medical use of cannabis. The court concluded that the prohibition infringed impermissibly upon the patient's constitutional rights to life, liberty and personal autonomy. While not binding precedent, it is instructive in its analysis of the constitutional rights at stake. The decision is available at http://www.ontariocourts.on.ca/decisions/2000//july/parker.pdf.

[37] The Cooperative has standing to assert the constitutional rights of patient-members. *NAACP v. Alabama*, 357 U.S. 449, 459 (1958). The patient-members have standing to assert these rights on their own behalf, the interests protected are germane to the purpose of the Cooperative, and the direct participation of patient-members is not required to decide these issues. *Warth v. Seldin*, 422 U.S. 490, 511 (1975).

patients have a fundamental right to be free from government interdiction of their personal self-funded medical decision, in consultation with their physician, to alleviate their suffering through the only alternative available to them. Under traditional Due Process analysis, that interest cannot be infringed absent government action that is narrowly tailored to serve a compelling state interest. *See Glucksberg*, 521 U.S. at 721.[38]

Due Process analysis begins with an examination of our "Nation's history, legal traditions and practices." *Id.* at 710. The uncontradicted record in this case establishes the ancient and long accepted use of cannabis as a medicine. J.A. 122-126. The common law contained no proscription against medical cannabis, and when the original 13 States ratified the Bill of Rights, cannabis was in use as a medicine. J.A. 123-124. Until 1941, cannabis was indicated for numerous medical conditions in the pharmacopoeia of the United States. While the liberty to use cannabis for medical purposes has a long tradition in America, the same cannot be said for the claim of federal power to control it. J.A. 124-125. Indeed, the first federal restriction on its sale was the Marihuana Tax Act of 1937.

Moreover, the liberty to use cannabis under conditions of medical necessity meets the requirements for a protected right identified by Justice Souter. First, the right is among "those truly deserving constitutional stature, either

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[38] The government mischaracterizes these claims by relying on cases such as *Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980) and *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980), for the proposition that there is no constitutional right to obtain a particular medical treatment. Pet.Br. 25 n.14. Unlike those cases, however, this case does not involve (a) an attempted governmental reclassification or approval of any drug, (b) a suit by persons for whom *no* medically effective treatment to save their lives is available, or (c) an attempt to gain access to a wholly experimental drug not shown to be effective.

to those expressed in constitutional text, or those exemplified by 'the traditions from which [the Nation] developed,' or revealed by contrast with 'the traditions from which it broke.' " *Glucksberg*, 521 U.S. at 767 (Souter, J., concurring). The right of privacy for personal and intimate decisions, the right of bodily integrity to be free of unnecessary pain, and the physician-patient relationship are each aspects of the inalienable right to life that is identified in the Declaration of Independence and explicitly protected by the text of the Fifth and Fourteenth Amendments. *Id.* at 777-779. Respondents' patients need cannabis to combat serious illness (such as cancer), to prolong their lives or to enable them to withstand the rigors of other treatments that are essential to prolonging their lives. It is difficult to imagine a right more fundamental or textually supported than the right to life.

Second, here "the legislation's justifying principle," such as it is, "critically valued, is so far from being commensurate with the individual interest as to be arbitrary or pointlessly applied that the statute must give way." *Id.* U.S. at 768 (Souter, J., concurring). There is simply no principled reason to deprive the class of seriously ill patients of the therapeutic benefits of cannabis. In the face of an interest as powerful as the avoidance of physical suffering, the restoration of health, and the preservation of life, "a State may not rest on threshold rationality or a presumption of constitutionality, but may prevail only on the ground of an interest sufficiently compelling to place within the realm of the reasonable a refusal to recognize the individual right asserted." *Id.* at 766. If any right is implicit in the concept of "ordered liberty," *Poe v. Ullman*, 367 U.S. 497, 549 (1961) (Harlan, J., dissenting), it is the right to seek medical assistance and to protect one's health and life by reasonable means that do not harm others.

Nor is the prohibition at issue here merely a "law that incidentally makes it somewhat harder to exercise a fundamental liberty." *Glucksburg*, 521 U.S. at 767 n.8 (Souter, J.,

concurring). Rather it is "law that creates a 'substantial obstacle,' for the exercise of a fundamental liberty interest." *Id.* at 767 (quoting *Planned Parenthood v. Casey*, 505 U.S. 833, 877 (1992)) and consequently "requires a commensurably substantial justification in order to place the legislation within the realm of the reasonable." *Id.* Under the terms of the amended injunction, cannabis is the *only* effective therapy available to a small number of patients facing dire health consequences. The government has offered no evidence to justify this significant interference with these patients' fundamental rights.

C. Prohibiting the Use of Cannabis in Cases of Medical Necessity Violates The Fundamental Liberties of the People Under the Fifth Amendment Due Process Clause or the Ninth Amendment and the Powers Reserved Under the Tenth Amendment.

Assuming *arguendo* that the prohibition of purely intrastate distribution of cannabis for medical purposes is necessary to effectuate Congress's power over interstate commerce, this prohibition must also be "proper," insofar as it does not intrude upon either the fundamental liberties of the people or on their sovereign reserved powers. This Court has recently noted one aspect of the "propriety" of means in *Printz v. United States*, 521 U.S. 898, 923-24 (1997): "When a 'Law for carrying into Execution' the Commerce Clause violates the principle of state sovereignty . . . it is not a 'Law . . . proper for carrying into Execution the Commerce Clause,' and is thus, in the words of The Federalist, 'merely [an] act of usurpation' which 'deserves to be treated as such.' The Federalist No. 33, at 204 (A. Hamilton)." Citing also Gary Lawson & Patricia Granger, *The 'Proper' Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 Duke L.J. 267, 297-326, 330-333 (1993). As Lawson & Granger have

shown, the historical meaning of "proper" had other dimensions as well:

> In view of the limited character of the national government under the Constitution, Congress's choice of means to execute federal powers would be constrained in at least three ways: . . . [E]xecutory laws must be consistent with principles of separation of powers, principles of federalism, and *individual rights*.

Id. at 297 (emphasis added).

The effect of fundamental liberties on the propriety of means by which Congress exercises its enumerated powers was also recognized in *United States v. Carolene Products*, 304 U.S. 144 (1938), which famously states that "there may be a narrower scope for operation of the presumption of constitutionality when legislation appears on its face to be within a specific prohibition of the Constitution, such as those of the first ten amendments. . . ." *Id.* at 152 n.4. Moreover, this Court has long recognized unenumerated liberties can be as fundamental as those that are enumerated. *See, e.g., Meyer v. Nebraska*, 262 U.S. 390 (1923) (right of parents to educate their children in the German language); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (right of parents to send their children to private Catholic school).

Although the protection of unenumerated liberties traditionally has been afforded under the Due Process Clause of the Fifth Amendment (*see* § III. B., *supra*), it would also be both textually and historically warranted under the Necessary and Proper Clause and under the Ninth Amendment's express injunction that "The enumeration in the Constitution of certain rights shall not be construed to deny or disparage others retained by the people." U.S. Const. Amend. IX. As Madison explained in his speech to the House on the Bill of Rights, the provision that became the Ninth Amendment was intended to negate any inference that "those rights which were not singled out, were

intended to be assigned into the hands of the General Government, and were consequently insecure." 1 Annals of Cong. 456 (1789). And in his speech to the Congress concerning the constitutionality of the national bank he explained that, while the Tenth Amendment "exclude[s] every source of power not within the Constitution itself," the Ninth Amendment "guard[s] against a latitude of interpretation" of the enumerated powers. 2 Annals. of Cong. 1951 (1791) (referring to the 11th and 12th article proposed to the states for ratification).

Members of this Court have strongly affirmed its power to identify and protect unenumerated liberties that are deemed "fundamental" in the same manner as those that are enumerated. *See, e.g., Planned Parenthood,* 505 U.S. at 848 (opinion of the Court relying in part on Ninth Amendment). Others have expressed doubts that judges should be entrusted with the task of identifying whether a particular liberty interest is or is not fundamental. *See, e.g., Troxel v. Granville,* 120 S. Ct. 2054, 2074 (2000) (Scalia, J., dissenting). This case, however, is both unusual and distinguishable from other unenumerated rights cases because here it is *the people themselves,* using powers reserved under the Tenth Amendment, who have recognized the fundamentality of the liberty interest in using cannabis to alleviate pain and preserve life. In nine states, voters have protected this liberty directly by popular referenda or ballot initiative. *See, e.g.,* Cal. Health and Safety Code § 11362.5(b)(1). In his *Troxel* dissent, Justice Scalia observed that it is "entirely compatible with the commitment to representative democracy set forth in the founding documents to argue, in legislative chambers or in electoral campaigns, that the state has no power to interfere with parents' authority over the rearing of their children. . . . " *Troxel,* 120 S. Ct. at 2074. (Scalia, J., dissenting). For the same reason, it is entirely compatible with the commitment to representative democracy for the people of a State,

acting through the initiative process, to declare that a particular liberty is fundamental, and for this Court to acknowledge and defer to their judgment. Indeed, four members of this Court concluded that the people of a State, amending their State Constitution by popular vote, could impose additional qualifications on their Representatives to Congress. *See U.S. Term Limits v. Thornton*, 514 U.S. 779, 845 (1995) (Thomas, J., dissenting).

Respondents agree that "[t]he States have no power, reserved or otherwise, over the exercise of federal authority within its proper sphere." *Id.* at 841 (Kennedy, J., concurring). Respondents do not contend that the people of a State can override a federal law any more than can their legislature. Rather, the people of California and their State using powers reserved under the Tenth Amendment, recognized a liberty to be worthy of legal protection. This justifies a federal court to subject a federal exercise of an implied power to meaningful scrutiny to determine whether it is indeed "within its proper sphere" to restrict such a liberty. In so doing, the court should give great deference to the people's judgment that a liberty interest is fundamental.[39]

This case represents an intersection of the Tenth and Ninth Amendments. The people have used the initiative power reserved to themselves under the Tenth Amendment to recognize a fundmental liberty interest they have retained under the Ninth Amendment. By an unwarranted

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[39] In affirming that the people may exercise their reserved powers to declare a liberty interest to be fundamental, Respondents do not suggest that this Court has no power to protect the rights of individuals and minorities from popular referenda and initiatives. To the contrary, this slippery slope has already been avoided by the limiting principle supplied in *Romer v. Evans*, 517 U.S. 620 (1996), invalidating an initiative amending the Colorado constitution on the ground it violated the Equal Protection Clause.

extension of its powers under the Necessary and Proper Clause, the federal government now seeks to interfere with both the exercise of the "power reserved" by the people and the States and the "rights retained" by the people.

Finding a liberty interest to be "fundamental" does not end the inquiry. It merely shifts the presumption to one favoring the individual, which the government may then overcome with an adequate showing. *See Carolene Products*, 304 U.S. at 152 n.4. Respondents agree with Justice Thomas' opinion that interferences with an unenumerated fundamental right should be subjected to strict scrutiny. *Troxel*, 120 S. Ct. at 2068 (Thomas, J., concurring).

In this case, the government has offered no evidence showing why a complete prohibition against the medical use of cannabis rather than appropriate regulation is necessary to further whatever governmental interest allegedly may exist. Nor has the government shown why the complete prohibition of cannabis for medical use is warranted in light of the availability of other substances for medical use such as morphine or cocaine.[40] For these reasons, the Court must conclude that the government's complete prohibition of all medical use of cannabis is unconstitutional.

CONCLUSION

Because federal courts retain their traditional equitable discretion to consider the hardship to seriously ill patients in fashioning injunctive relief under the CSA, the judgment of the Court of Appeals should be affirmed.

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[40] For these reasons, the application of the CSA to prohibit the medical use of cannabis would also fail intermediate scrutiny, an "undue burden" standard, and even the rational basis test employed by the Court in *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432 (1985) or in *Romer v. Evans*, 517 U.S. 620 (1996).

Alternatively, because the CSA does not foreclose the defense of medical necessity, the judgment of the Court of Appeals should be affirmed. Any other interpretation of the CSA would render the statute unconstitutional, exceed Congress's powers under the Commerce Clause, violate the Ninth and Tenth Amendments, and deny the fundamental rights of seriously ill patients.

Respectfully submitted,

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February 20, 2001

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1. Section 801 of Title 21 of the United State Code states in relevant part as follows:

Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

2. Section 903 of Title 21 of the United State Code states in relevant part as follows:

Application of State law

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

3. The Fifth Amendment to the Constitution states as follows:

AMENDMENT V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

4. The Ninth Amendment to the Constitution states as follows:

AMENDMENT IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

5. The Tenth Amendment to the Constitution states as follows:

AMENDMENT X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

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No. 00-151

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

The Controlled Substances Act (CSA) bans the unauthorized distribution of marijuana for all purposes, including purported medical uses, 21 U.S.C. 841(a)(1), and authorizes courts to enjoin violations of the Act. 21 U.S.C. 882. Respondents nonetheless ask this Court to hold that they may not be enjoined from distributing marijuana for medical purposes, even though marijuana is a schedule I controlled substance and has never been approved by the Food and Drug Administration (FDA) as safe and effective to treat any medical condition. To justify that result, respondents argue that the CSA does not clearly preclude a common law defense of "medical necessity" (Br. 17-22), that in any event a court has equitable power to decline to enjoin the illegal distribution of marijuana for medical purposes (Br. 11-17), and, finally, that if the CSA does not contain a defense of medical necessity then it is unconstitutional (Br. 27-50). Each of those arguments lacks merit.

1. *The Act forecloses a common law "medical necessity" defense*

a. Respondents argue (Br. 17-21, 29) that a common law defense of "medical necessity" is no more precluded by the CSA than a common law defense of entrapment or duress. But this argument ignores the fact that the common law defense of necessity by its own terms exists only where the legislature has not manifested a contrary intent. Here, the CSA clearly manifests the intent to prohibit the illegal distribution of marijuana for claimed medical purposes.

Respondents urge (Br. 16) the Court to look beyond the text of the CSA to "our broader notions of justice and common sense," and contend on this basis (Br. 21-22, 24-25) that, while the CSA generally bars the unauthorized distribution or use of marijuana, Congress did not intend to bar such conduct when a jury determines in a particular case that

marijuana is medically efficacious and that lawful drugs are ineffective at treating a user's pain and suffering.

But banning marijuana in those circumstances is precisely what Congress did do in the CSA, by imposing criminal sanctions for the distribution of controlled substances—*drugs*—that otherwise could be put to medical use. See 21 U.S.C. 321(g)(1) ("The term 'drug' means * * * articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man."); 21 U.S.C. 802(6) (the term "controlled substances" means a scheduled "drug"); 21 U.S.C. 802(12) (incorporating 21 U.S.C. 321(g)(1)). Since its enactment in 1970, the CSA has made it a crime to "manufacture, distribute, or dispense" marijuana, "[e]xcept as authorized by" the Act itself (21 U.S.C. 841(a)(1))—*i.e.*, unless the person handling the marijuana is registered with the DEA to conduct research approved by the FDA (21 U.S.C. 355(i) and 823(f)), or the Attorney General, after consultation with the Secretary of Health and Human Services (HHS), determines under 21 U.S.C. 811 that marijuana no longer meets the statutory criteria for a schedule I controlled substance of having "no currently accepted medical use in treatment in the United States," "a high potential for abuse," and "a lack of accepted safety for use * * * under medical supervision," 21 U.S.C. 812(b)(1).

Consistent with that plain text, the CSA's structure and purposes conclusively demonstrate that Congress did not intend to permit juries to excuse the illegal distribution of marijuana based on a claimed need to avert medical harm. As explained in our opening brief (at 20-23), the CSA imposes stringent and uniform controls on the handling of all controlled substances, even those drugs that are listed in schedules II through V because there is a "currently accepted medical use" for the drugs and thus doctors may prescribe them to patients, 21 U.S.C. 812(b)(2)-(5). *A fortiori*, Congress did not intend to permit a schedule I drug, which has no currently accepted medical use, to be distri-

buted for medical purposes outside the strict confines of the Act itself.

A "medical necessity" defense would be utterly inconsistent with the provisions of the CSA requiring handlers to comply with DEA registration, production quotas, reporting, record-keeping, and order-form requirements, and, for schedules II through V drugs, prescription requirements. 21 U.S.C. 821-829. Contrary to respondents' characterization of those controls as requiring the "bureaucratic completion of a paper trail for every transfer of a pill" (Br. 24), those controls are essential to effectuate Congress's intent to create a closed system of drug distribution to combat the dangers of drug abuse and diversion. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 3, 6 (1970); see also *United States* v. *Moore*, 423 U.S. 122, 135, 141 (1975); U.S. Br. 6, 21-22.[1]

This Court also should take no comfort in respondents' representation (Br. 9, 17-19) that they intend to distribute marijuana to only a "minuscule" number of persons who face "death, blindness, or starvation." The Ninth Circuit's decision invites district courts to permit the illegal distribution of marijuana to *any* person who has a "serious medical condition[]" and whose physician "certifies[]" that legal drugs "are ineffective" or "result in intolerable side effects." App. 7a, 39a.[2] The court's decision places no limit on the number of people to whom respondents may distribute marijuana or the quantity of marijuana that they may distribute, either in the aggregate or to particular customers. Even if

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[1] By contrast, respondents' self-imposed "protocols," which bar smoking on their premises and require members to receive identification cards, undergo screening interviews, and provide a verifiable doctor's note assenting to marijuana "therapy," App. 3a-4a & n.4, bear no resemblance to the CSA's comprehensive and unified set of controls.

[2] The express terms of the district court's orders do not even require a doctor's certification of medical necessity. See App. 33a-35a.

the recognition of a "medical necessity" defense could be confined to the distribution of marijuana (and no other schedule I drugs)—and there is no basis to conclude that it could—the court's decision seriously undermines the effectiveness and administration of the Act.

As we also explain in our opening brief (at 23-25), a "medical necessity" defense is directly contrary to the CSA's exclusive rescheduling provisions, 21 U.S.C. 811, 812, which give the Attorney General, after consultation with the Secretary of HHS, the authority to determine whether marijuana has an accepted medical use. Those rescheduling provisions authorize judicial review of any final decision by the Attorney General declining to reschedule a controlled substance, 21 U.S.C. 877, but in the absence of a rescheduling decision, they leave no room for district courts or juries to determine on a case-by-case basis whether marijuana may be used as medicine.

Finally, any question regarding congressional intent is put to rest by the statutory provision enacted by Congress in 1998 entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE." Act of Oct. 21, 1998, Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. That provision reiterates that drugs are placed in schedule I precisely because they "lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision"; that marijuana has not been approved by the FDA "to treat any disease or condition"; and that Congress "opposes efforts to circumvent" the drug approval process "by legalizing marijuana * * * for medicinal use without valid scientific evidence and the approval of the [FDA]." *Ibid.* Those statutory recitations confirm Congress's determination not only that marijuana lacks any accepted medical utility, but also that marijuana may not be used to treat any medical

condition unless and until the FDA finds that marijuana is safe and effective.[3]

Respondents attempt to diminish the force of the 1998 legislation by arguing (Br. 34) that neither court below "purported to 'legalize' marijuana." Judicial authorization to distribute marijuana where the Act does not allow it, however, *does* "legaliz[e] marijuana * * * for medicinal use." 112 Stat. 2681-761. Respondents also observe (Br. 35) that the 1998 statute "makes no mention of necessity." But as we explain in our opening brief (at 17-19), a necessity defense is foreclosed when its application would fatally clash with the criminal statute's language, structure, or purpose. The CSA prohibits the unauthorized distribution of marijuana for all purposes, and the 1998 legislation confirms that prohibition with respect to the use of marijuana for asserted medical purposes.[4]

b. Respondents argue (Br. 23-24) that by placing marijuana in schedule I, and defining the criteria for schedule I to include no currently accepted medical use," 21 U.S.C. 812(b)(1), Congress did not itself determine that marijuana has "no currently accepted medical use," but merely limited the Attorney General's authority to change its classification. That argument defies logic. By placing marijuana in schedule I, Congress banned the unauthorized distribution of marijuana for all purposes, unless and until the Attorney General affirmatively determines that marijuana no longer meets schedule I's criteria of having "no currently accepted

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[3] A "medical necessity" defense also cannot be reconciled with the statutory and regulatory schemes under the CSA and the FDCA that reject the medical use of illegal drugs based on patients' and physicians' subjective views or anecdotal accounts, "no matter how fervently held," that the drug is safe and effective. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973); see U.S. Br. 31-34.

[4] For similar reasons, respondents err in relying (Br. 27-28) on the rule of lenity, which has no application unless this Court "can make no more than a guess as to what Congress intended." *Holloway* v. *United States*, 526 U.S. 1, 12 n.14 (1999) (internal quotation marks omitted).

medical use in treatment in the United States," "a high potential for abuse," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).[5] It would have made no sense for Congress to authorize the Attorney General to remove marijuana from schedule I in the event he determines that the drug no longer meets those criteria, unless Congress had made the initial judgment that it did meet the criteria. See 21 U.S.C. 812(c) (listing schedule I drugs "unless and until amended" by the Attorney General under 21 U.S.C. 811); see also 116 Cong. Rec. 1664 (1970) (statement of Sen. Hruska) ("Marijuana is included in schedule I since it comes squarely within the criteria of that schedule.").

c. Respondents further argue (Br. 28-31) that the CSA countenances some medical use of marijuana because HHS continues to supply eight individuals with marijuana for medical use pursuant to single-patient investigational new drug (IND) exemptions under 21 U.S.C. 355(i) and 823(f).[6]

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[5] For example, as respondents and their amici observe (Resp. Br. 23 n.19; Sheriff Dion *et al.* Br. 11), Congress has directed the Attorney General to place in schedule I methaqualone and gamma-hydroxybutyrate that is not contained in a drug product approved by the FDA, so that those drugs would be subject to the CSA's most stringent controls and banned for all purposes, including medical uses. Hillory J. Farias & Samantha Reid Date-Rape Drug Prohibition Act of 2000, Pub. L. No. 106-172, 114 Stat. 7; Act of June 29, 1984, Pub. L. No. 98-329, 98 Stat. 280. Those directives demonstrate that Congress would not want a jury, acting pursuant to a common law "medical necessity" defense, to override its judgment regarding the medical use of those drugs.

[6] Under single-patient IND exceptions, the FDA permits a doctor to give an unapproved, investigational drug to a single patient. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of subjects and to help assure the quality of the scientific evaluation of the drug's safety and effectiveness. See 21 C.F.R. 312.22. In the case of a single-patient IND, the patient is not part of a controlled clinical trial intended to determine whether the drug is safe and/or effective. We have been informed by the FDA that, for that reason, single-patient INDs do not provide much information that assists the agency in determining whether the drug is safe or effective.

That contention, however, confuses the limited and controlled distribution of marijuana by the *federal government* pursuant to *statute* with the illegal and unregulated distribution of marijuana by private parties. Those limited IND exemptions thus are fully consistent with Congress's intent to ban the distribution of marijuana for all purposes, including purported medical uses, except as controlled under the Act. In any event, HHS's single-patient INDs do not support the medical use of marijuana. In 1992, HHS ceased granting the INDs because the "widespread use of marijuana for medical purposes * * * is bad public policy and bad medical practice." *Kuromiya* v. *United States*, 78 F. Supp. 2d 367, 369 (E.D. Pa. 1999). Moreover, the government "never conceded formally that marijuana was effective in treating the symptoms of those individuals who were receiving it," *id.* at 369, and "consistently expressed skepticism about [the single-patient INDs] and the efficacy of using marijuana." *Id.* at 372.

d. Respondents purport (Br. 32-34) to find support for a *federal* "medical necessity" defense in the fact that some States have enacted statutes that carve out an exception to blanket statutory prohibitions similar to those in the CSA in order to authorize limited medical uses of marijuana. But because Congress did not enact such a statute, the cited state provisions point in precisely the opposite direction, demonstrating that when legislatures want to provide exceptions for some medical use of marijuana they know how to do so. Therefore, the absence of any exception in the CSA for medical use, coupled with Congress's steadfast adherence to the placement of marijuana in schedule I and its 1998 rejection of a "medicinal" use exception (112 Stat. 1281-761), clearly reflects Congress's intent to foreclose a common law necessity defense that would circumvent the CSA's strict prohibitions and controls.

2. *Courts lack the equitable power to permit the illegal distribution of marijuana based on a claimed medical need*

Respondents and their amici argue that this Court need not decide whether "medical necessity" is a valid legal defense under the Act, because the court of appeals' decision may be upheld on the ground that a district court has the equitable discretion under 21 U.S.C. 882 to refuse to enforce the CSA if the court determines that the balance of the equities favors the availability of marijuana for medical purposes. A district court undoubtedly has discretion to fashion an injunction under the CSA in the manner best suited to terminate violations of and secure compliance with the Act. U.S. Br. 37-43. But a federal court's equity power does not allow it to countenance ongoing violations of the CSA by refusing to enjoin the distribution of marijuana for medical purposes on the ground that there is a public interest in such use, in the face of Congress's contrary balancing of the relevant scientific, medical, and public policy considerations.[7]

a. As we explain in our opening brief (Br. 37-43), this Court's precedents confirm that when the United States brings an action for an injunction to enforce an Act of Congress, the court must exercise its equitable discretion in light of the text, structure, and underlying policies of the

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[7] Not even the court of appeals held that a district court may "ignore the law" in light of its view of the public interest. App. 8a. Rather, the court held that the district court abused its discretion in enjoining respondents' distribution of marijuana for all purposes, including medical uses, because the court failed "to take into account a legally cognizable defense" under the CSA. *Ibid.*; see also *id.* at 9a (explaining that, by seeking an injunction, "the government invited an inquiry into whether the injunction" should be "broad enough to prohibit *illegal* conduct, but narrow enough to exclude conduct that likely would be *legally privileged or justified*") (emphasis added); *ibid.* (finding that modification of the injunction would not conflict with the CSA's underlying policies); *id.* at 11a (remanding for district court to consider whether respondents met "the criteria for a medical necessity exemption").

statute that the court is charged with enforcing. Thus, *United States* v. *Rutherford*, 442 U.S. 544 (1979), held that a district court lacked the power to enter an injunction permitting the physician-supervised use of Laetrile by terminally ill cancer patients, because the FDCA "makes no special provision for drugs used to treat terminally ill patients." *Id.* at 551; U.S. Br. 27-28, 39. The CSA likewise "makes no special provision" for the unauthorized distribution of marijuana for medical purposes, regardless of whether a court sitting in equity is of the view that such distribution is "medically necessary." Congress already has determined that the unauthorized distribution of controlled substances, including marijuana, has "a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C. 801(2), and therefore has banned their unauthorized use. A court thus cannot defeat those policy judgments based on its own view that they are unwise or unfair. *Rutherford*, 442 U.S. at 551, 555, 559.[8]

b. Respondents also argue (Br. 12, 16) that a court may refuse to enjoin violations of the CSA when the government makes the "tactical" choice to forgo a criminal prosecution. In their view (Br. 16), a court may "require" the government to enforce the CSA solely by bringing a criminal prosecution, in which, they assert, a jury could take a "dim view of the governmental attempt to deprive grievously ill citizens of medication essential for relief during the last days of their lives."

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[8] Respondents attempt (Br. 35-37) to distinguish *Rutherford* on the ground that "[t]here was no credible evidence * * * that Laetrile was a cancer cure," whereas marijuana is the only drug of "proven effectiveness" for their members' conditions. *Rutherford* cannot credibly be read, however, as turning on the plaintiffs' inability to "prove" to a *court* that Laetrile was medically advantageous. Rather, *Rutherford* held that Congress had banned the use of Laetrile absent a finding by the *FDA* that the drug was safe and effective, as required by the FDCA. 442 U.S. at 551-559. Congress likewise has banned the medical use of marijuana absent FDA approval and rescheduling by the Attorney General.

The Act authorizes the Attorney General and not a court, however, to decide whether to enforce the Act through criminal or civil proceedings. A district court has no authority to refuse to enjoin flagrant and ongoing violations of the Act on the ground that the court believes the government should have proceeded criminally instead. It would defeat Congress's decision to authorize enforcement through civil injunctive relief if a court could decline to enforce the Act on the ground that the government did not seek the more onerous form of relief.[9]

Respondents' contention fails for another reason. Although a jury may have the *de facto* power to render a criminal verdict of acquittal "in the teeth of both law and facts," *Horning* v. *District of Columbia*, 254 U.S. 135, 138 (1920), a court has no authority to instruct a jury that it has that power, see, *e.g.*, *United States* v. *Edwards*, 101 F.3d 17, 19-20 (2d Cir. 1996) (collecting cases), or to exercise it itself. A court likewise has no discretion to refrain from enjoining ongoing violations of the Act on the ground that a jury might find the violations sympathetic and therefore nullify the Act.

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[9] For similar reasons, amici ACLU *et al.* err in contending (Br. 21-27) that a court should refrain from enjoining violations of the CSA because, although the CSA provides for a trial by jury in instances of an alleged violation of a civil injunction, see 21 U.S.C. 882(b), contempt proceedings lack some of the procedural safeguards of a criminal trial. Amici ACLU *et al.* also contend (Br. 14 n.7) that the district court's orders on remand leave the government "a viable alternative" of pursuing a criminal prosecution against respondents. That alternative hardly seems "viable" in light of the Ninth Circuit's recognition of a "medical necessity" defense and the district court's orders that permit respondents to violate the Act.

3. *The CSA's ban on marijuana distribution for medical purposes satisfies constitutional requirements*

Respondents and their amici argue that the CSA should not be construed to foreclose a "medical necessity" defense in order to avoid what they assert is a difficult constitutional question. As respondents recognize (Br. 37), however, that canon of construction has no application absent statutory ambiguity. *Whitman* v. *American Trucking Ass'ns*, 121 S. Ct. 903 (2001). As we explain above and in our opening brief, Congress spoke with unmistakable clarity in precluding the illegal distribution of marijuana despite a claimed "medical necessity." Moreover, all of the constitutional challenges, to the extent they are properly before this Court, lack merit.[10]

a. Respondents argue (Br. 37-41) that Congress lacks the power under the Commerce Clause, Art. I, § 8, Cl. 3, to ban the intrastate distribution of marijuana for medical purposes. That is not correct.[11] Congress's commerce authority

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[10] The court of appeals did not address respondents' constitutional claims, and respondents did not raise the Commerce Clause challenge in the court of appeals. Moreover, respondents did not mention the Ninth and Tenth Amendments in their brief opposing certiorari, although they stated in a footnote in their brief opposing the government's motion to stay the district court's remand orders that the court of appeals' decision could be supported on Ninth and Tenth Amendment grounds. Stay Opp. 10 n.2. Finally, as we note in our certiorari petition (at 5 n.5), respondents' substantive due process claim is currently before the district court on remand from the Ninth Circuit.

[11] Every court of appeals has upheld the constitutionality of the CSA under the Commerce Clause. *United States* v. *Edwards*, 98 F.3d 1364, 1369 (D.C. Cir. 1996), cert. denied, 520 U.S. 1170 (1997); *United States* v. *Lerebours*, 87 F.3d 582, 584-585 (1st Cir. 1996), cert. denied, 519 U.S. 1060 (1997); *United States* v. *Genao*, 79 F.3d 1333, 1336-1337 (2d Cir. 1996); *United States* v. *Orozco*, 98 F.3d 105, 107 (3d Cir. 1996); *United States* v. *Leshuk*, 65 F.3d 1105, 1112 (4th Cir. 1995); *United States* v. *Clark*, 67 F.3d 1154, 1165-1166 (5th Cir. 1995), cert. denied, 517 U.S. 1141 (1996); *United States* v. *Tucker*, 90 F.3d 1135, 1140-1141 (6th Cir. 1996); *United States* v. *Westbrook*, 125 F.3d 996, 1009-1010 (7th Cir.), cert. denied, 522 U.S. 1036 (1997); *United States* v. *Brown*, 72 F.3d 96, 97 (8th Cir. 1995) (per curiam),

includes the power to regulate intrastate economic activity that substantially affects interstate commerce. *United States* v. *Morrison*, 529 U.S. 598, 611-612 (2000); *United States* v. *Lopez*, 514 U.S. 549, 559-560 (1995)).[12] Marijuana distribution is economic activity. See, *e.g.*, *United States* v. *Orozco*, 98 F.3d 105, 107 (3d Cir. 1996) ("drug trafficking is an inherently commercial activity"); *United States* v. *Rogers*, 89 F.3d 1326, 1338 (7th Cir.) ("drug dealing is an economic activity"), cert. denied, 519 U.S. 999 (1996). Marijuana is a tradable commodity for which there exists a substantial and national market. 21 U.S.C. 801(3) ("A major portion of the traffic in controlled substances flows through interstate and foreign commerce."). Indeed, respondents do not dispute that they *sell* marijuana to their members. See J.A. 50 ("marijuana for sale * * * ranged in price from between $28 to $85 per one-eighth ounce"), J.A. 60 (20 grams of "Afghani Hash" sold for $400); see also J.A. 64-65, 72.[13]

Respondents therefore err in arguing (Br. 39-41) that the CSA cannot constitutionally be applied to their intrastate drug distribution for medical purposes because the government has not shown that particular activity to substantially affect interstate commerce. "[W]here a general regulatory statute bears a substantial relation to commerce, the de

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cert. denied, 518 U.S. 1033 (1996); *United States* v. *Tisor*, 96 F.3d 370, 373-375 (9th Cir. 1996), cert. denied, 519 U.S. 1140 (1997); *United States* v. *Wacker*, 72 F.3d 1453, 1475 (10th Cir. 1995), cert. denied, 523 U.S. 1035 (1998); *United States* v. *Jackson*, 111 F.3d 101, 102 (11th Cir.), cert. denied, 522 U.S. 878 (1997).

[12] The activities regulated by the statutes at issue in *Morrison* and *Lopez* were found to be non-economic in nature. *Morrison*, 529 U.S. at 617 (gender-motivated violence covered by Violence Against Women Act of 1994, 42 U.S.C. 13981); *Lopez*, 514 U.S. at 551, 561, 567 (gun possession in a local school zone banned by Gun-Free School Zones Act of 1990, 18 U.S.C. 922(q)(1)(A)).

[13] Respondents' alleged non-profit character (Br. 2; J.A. 29) does not exempt them from Congress's Commerce Clause authority. See *Camps Newfound/Owatonna, Inc.* v. *Town of Harrison*, 520 U.S. 564, 583-586 (1997).

minimis character of individual instances arising under that statute is of no consequence." *Lopez*, 514 U.S. at 558 (emphasis and internal quotation marks omitted); see also *Perez* v. *United States*, 402 U.S. 146, 154 (1971); *Maryland* v. *Wirtz*, 392 U.S. 183, 192 (1968); *United States* v. *Darby*, 312 U.S. 100, 120-121 (1941). For example, in *Wickard* v. *Filburn*, 317 U.S. 111 (1942), the Court upheld federal regulation of wheat grown and consumed on a family farm in order to control the volume of wheat moving in interstate and foreign commerce. See *Lopez*, 514 U.S. at 559-561; *Morrison*, 529 U.S. at 610-611.

Respondents argue (Br. 41 n.35) that *Wickard* is inapposite because, unlike the wheat at issue in *Wickard*, "there is no federal scheme of price maintenance" for marijuana affected by respondents' intrastate activities. The intrastate distribution of marijuana for medical purposes, however, substantially affects the interstate market for marijuana by increasing the drug's demand and supply, and by interfering with the CSA's purpose to establish a national and uniform closed system to prevent the abuse and diversion of illegal drugs. See 21 U.S.C. 801(4) (finding that "[l]ocal distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances."); 21 U.S.C. 801(6) (finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic").[14] As the district court explained in rejecting

[14] Congress in the CSA also found that "[i]ncidents of the [drug] traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a *substantial and direct effect upon interstate commerce* because – (A) after manufacture, many controlled substances are transported in interstate commerce, (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession." 21 U.S.C. 801(3) (emphasis added).

respondents' Commerce Clause challenge, "[m]edical marijuana may be grown locally, or out of the state or country, and there is nothing in the nature of medical marijuana that limits it to intrastate cultivation. Similarly, it may be transported across state lines and consumed across state lines. * * * [Marijuana] distribution [is] a class of activities that, even if done for the humanitarian purpose of serving the legitimate health care needs of seriously ill patients, can affect interstate commerce." App. 59a.

b. Nor is there any merit to the suggestion of respondents and their amici (see, *e.g.*, Resp. Br. 45-49) that banning respondents' distribution of marijuana would violate the Tenth Amendment because Proposition 215 reflects the State of California's determination that marijuana has medical utility.

This Court "long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers" or that "curtail[s] or prohibit[s] the States' prerogatives to make legislative choices respecting subjects the States may consider important." *Hodel* v. *Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 290, 291 (1981). Thus, in the absence of federal "commandeer[ing of] the state legislative process by requiring a state legislature to enact a particular kind of law," *Reno* v. *Condon*, 528 U.S. 141, 149 (2000), the Tenth Amendment "states but a truism that all is retained which has not been surrendered," *Darby*, 312 U.S. at 124. "If a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States," *New York* v. *United States*, 505 U.S. 144, 156 (1992). Because the CSA's generally applicable prohibition against manufacture, distribution, and possession of marijuana is a valid exercise of Congress' Commerce Clause authority, pp. 11-13, *supra*, that prohibition does not

violate the Tenth Amendment. See, *e.g.*, *Reno*, 528 U.S. at 149-150 (rejecting Commerce Clause and Tenth Amendment challenges to federal statute imposing civil and criminal penalties upon state and private actors for improper disclosure of certain state motor vehicle records); see also *United States* v. *Westbrook*, 125 F.3d 996, 1010 (7th Cir.) (rejecting Tenth Amendment challenge to CSA), cert. denied, 522 U.S. 1036 (1997); accord *United States* v. *Lerebours*, 87 F.3d 582, 585 (1st Cir. 1996), cert. denied, 519 U.S. 1060 (1997); *United States* v. *Owens*, 996 F.2d 59, 60-61 (5th Cir. 1993).

Moreover, nothing in Proposition 215 purports either to override federal law or to legalize the distribution of marijuana for medical purposes.[15] Rather, Proposition 215 exempts from the State's own criminal laws the possession and cultivation of marijuana for medical use by a "patient[] or [the] patient's primary care-giver * * * upon the oral or written recommendation or approval of a physician." Cal. Health & Safety Code § 11362.5(d) (West 2001). Proposition 215 therefore does not authorize respondents' conduct.[16] Indeed, the State itself has successfully closed "medical-marijuana" distribution clubs because they violate California's laws that *criminalize* the selling, furnishing, or giving

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[15] Because there is no occasion in this case to determine whether Proposition 215 conflicts with the CSA, respondents' reliance (Br. 9) on 21 U.S.C. 903, which provides that the CSA shall not be construed to displace state law absent "positive conflict" with state law, is inapposite.

[16] For that reason, respondents err in suggesting (Br. 16) that the district court could exercise its discretion to decline "to restrain state officers in the administration of state law." In any event, even if we assume, arguendo, that respondents are "state officers" because the City of Oakland has designated them to administer the City's marijuana distribution "Program," J.A. 146, respondents would not be permitted to distribute marijuana in violation of federal law. *Condon*, 528 U.S. at 149-150; cf. 21 U.S.C. 885(d) (providing immunity under CSA for state officials "engaged in the enforcement" of controlled substances laws).

away of marijuana. *People* v. *Peron*, 70 Cal. Rptr. 2d 20, 25-28 (1997), review denied (Feb. 25, 1998).[17]

c. Respondents and their amici further argue (see, *e.g.*, Resp. Br. 42-49) that individuals have a Ninth Amendment and substantive due process right to use marijuana when doctors and their patients conclude that such use is "medically necessary." Respondents and their amici have not established, however, that the use of a *particular* drug (much less the receipt of the drug from a distributor), free of a regulatory regime designed to protect the public health and safety, is a fundamental right that is deeply rooted in "our Nation's history, legal traditions, and practices." *Washington* v. *Glucksberg*, 521 U.S. 702, 710 (1997); cf. *Employment Div., Dep't of Human Res. of Or.* v. *Smith*, 494 U.S. 872 (1990) (rejecting claim of Free Exercise right to religiously motivated peyote use).[18]

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[17] Respondents err in asserting (Br. 1 n.2) that marijuana distribution is not authorized by Proposition 215 because one of its purposes is to "*encourage* the federal and state governments to implement a *plan* to provide for the safe and affordable distribution of marijuana to all patients in medical need." Cal. Health & Safety Code § 11362.5(b)(1)(C) (West 2001) (emphases added); see also *Peron*, 70 Cal. Rptr. 2d at 28 (rejecting contention that Section 11362.5(b)(1)(C) indicates an intent to authorize the distribution of small amounts of marijuana for medical purposes, explaining that the "drafters [of Proposition 215] were aware of both state and federal law prohibiting such sales and were attempting to avoid a conflict therewith"). Equally irrelevant is respondents' observation (Br. 1 n.2) that the district court "assumed" that state law applied to respondents' conduct in order "to avoid a factual dispute." App. 47a.

[18] The lower courts repeatedly have held that governmental regulations designed to protect health and safety do not infringe a fundamental right merely because they restrict a patient's choice of a particular medical treatment. See, *e.g.*, *Mitchell* v. *Clayton*, 995 F.2d 772, 775-776 (7th Cir. 1993) ("[a] patient does not have a constitutional right to obtain a particular type of treatment * * * if the government has reasonably prohibited that type of treatment"); *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (per curiam) ("[c]onstitutional rights of privacy and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power"); *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.) (a patient's "selection of a particular

Such a right would be inconsistent with this country's history of restrictions on the distribution and use of medicinal and "street" drugs. As early as 1736, Virginia began to regulate the practice of pharmacy, and by the time of the Civil War, four States had similar laws. Pharmaceutical regulation intensified in the period after the Civil War, such that by 1900, with the exception of Nevada, every State had passed laws regulating the practice of pharmacy, and at least 25 States or territories had passed laws prohibiting drug adulteration and regulating the sale of poisons. 37 David L. Cowen, *Pharmacy in History: The Development of State Pharmaceutical Law* 49-50 (1995).

In 1906, Congress passed the Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, to prohibit the manufacture of adulterated or misbranded food or drugs. In 1914, Congress passed the predecessor to the CSA, the Harrison Narcotics Act, ch. 1, 38 Stat. 785, which restricted the use of narcotics such as opium, morphine, and cocaine in order to combat the problems of abuse and addiction. Cf. *Moore*, 423 U.S. at 132 (noting that "[p]hysicians who stepped outside the bounds of professional practice could be prosecuted under the [Harrison Act]."). In 1938, Congress passed the FDCA, which requires FDA approval of drugs in order to "protect the public health by ensuring that . . . drugs are safe and effective." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) (quoting 21 U.S.C. 393(b)(2) (1994 & Supp. III 1997)); accord *United States* v. *Walsh*, 331 U.S. 432, 434 (1947).

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treatment, or at least a medication, is within the area of governmental interest in protecting public health"), cert. denied, 449 U.S. 937 (1980); *Kuromiya* v. *United States*, 37 F. Supp. 2d 717, 726 (E.D. Pa. 1999) (rejecting constitutional challenge to CSA by individuals seeking to use marijuana for medical purposes, concluding that "there is no fundamental right of privacy to select one's medical treatment without regard to criminal laws"); see also U.S. Br. 25 n.14.

After marijuana use in this country first became popular among limited segments of the population in the mid-1920s, the National Conference of Commissioners on Uniform State Laws in 1932 recommended passage of the Uniform Narcotic Drug Act, which included an optional provision to list marijuana as a narcotic subject to strict controls. By 1937, every State, either by adoption of the Uniform Act or by separate legislation, had restricted or prohibited marijuana use. R.J. Bonnie & C.H. Whitebread, *The Marihuana Conviction* 31-52, 79-91 (1974); National Comm'n on Marihuana & Drug Abuse, *Marihuana: A Signal Of Misunderstanding* 13-14, 104-105 (Mar. 1972). Also in 1937, Congress passed the Marihuana Tax Act, ch. 553, 50 Stat. 551, which severely restricted the use of and trafficking in marijuana, even for medical purposes. *United States* v. *Sanchez*, 340 U.S. 42, 43-44 (1950); see also R.J. Bonnie & C.H. Whitebread, *supra*, at 165. That long-standing tradition of governmental regulation to protect the public from unsafe or improperly diverted drugs (including marijuana) cannot be reconciled with the assertion of a fundamental right to use a particular drug (including marijuana) free of governmental regulation to protect the public health and safety.

There is also no basis for concluding that Congress has infringed on the liberty interests of individuals who seek to relieve their pain and suffering. The CSA does not deprive citizens of the ability to obtain medication to treat disease or relieve pain and suffering. Rather, the CSA outlaws the unauthorized use of a particular unapproved drug, marijuana, based on judgments made by Congress, the Secretary of Health and Human Services, and the Attorney General that marijuana has no currently accepted medical use, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Congress, the Secretary, and the Attorney General made that determination in furtherance of their obvious and compelling interest in combating drug abuse and protecting the public from the dangers associated

with the use of unsafe drugs that may be diverted for improper purposes. See *National Treasury Employees Union* v. *Von Raab*, 489 U.S. 656, 668, 674 (1989) (observing that drug trafficking is "one of the greatest problems affecting the health and welfare of our population" and that "drug abuse is one of the most serious problems confronting our society today"); see also *Smith*, 494 U.S. at 905 (O'Connor, J., concurring) (State has a "compelling" and "overriding interest in preventing the physical harm caused by the use of a Schedule I controlled substance").

Congress, moreover, has ensured that government restrictions on controlled substances are well-founded. The CSA authorizes research with respect to possible medical uses of marijuana, albeit under the strict confines of the Act. See 21 U.S.C. 823(f); see also 21 U.S.C. 355(i). The CSA permits the Attorney General to reschedule marijuana if he determines that marijuana no longer meets the criteria of a schedule I drug, including that it has "no currently accepted medical use." 21 U.S.C. 811, 812(b)(1)(B). The FDCA similarly authorizes the FDA to approve marijuana for medical use if it finds that marijuana is safe and effective for any intended medical use. 21 U.S.C. 355. Congress also has authorized courts to review final agency action under those Acts and to overturn those that are arbitrary or capricious or not supported by substantial evidence. 21 U.S.C. 355(h), 877.[19]

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[19] Although respondents and their amici express their belief in the therapeutic benefits of marijuana and their frustration with the potentially time-consuming process of rescheduling marijuana or obtaining FDA approval of the drug, they have not petitioned the DEA to reschedule marijuana based on a claim that it has a "currently accepted medical use," see U.S. Br. 24 & n.12, and they do not assert that they have requested the FDA to approve marijuana as safe and effective for any medical condition.

As we noted in our opening brief (at 24 n.12), on July 10, 1995, Jon Gettman petitioned the DEA to initiate rulemaking proceedings to reschedule marijuana on the asserted ground that marijuana lacks a high

Finally, there is nothing inherently suspect about Congress's medical and policy judgments regarding marijuana. All citizens have an interest in obtaining medication that is "proven" to treat disease or to relieve the pain and suffering of those who are sick or terminally ill. Therefore, "[t]here is no reason to think the democratic process will not strike the proper balance" between the interest of those individuals and Congress's interest in ensuring that drugs are safe and effective and are not used or diverted for improper purposes. *Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring); cf. *City of Cleburne* v. *Cleburne Living Ctr., Inc.*, 473 U.S. 432, 445 (1985).

* * * * *

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

BARBARA D. UNDERWOOD
Acting Solicitor General

MARCH 2001

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potential for abuse. By letter dated March 20, 2001, the Administrator of DEA notified Mr. Gettman that his petition was denied, explaining that both the DEA and HHS have concluded that marijuana continues to meet the criteria for placement in schedule I of having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use even under medical supervision. We are lodging with the Court the DEA's response to Mr. Gettman's petition, which also contains the scientific and medical recommendation that HHS's Assistant Secretary for Health and Surgeon General provided to the Administrator on January 17, 2001.

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No. 00-151

In The

Supreme Court of the United States

UNITED STATES,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE INSTITUTE ON GLOBAL DRUG POLICY OF THE DRUG FREE AMERICA FOUNDATION; NATIONAL FAMILIES IN ACTION; DRUG WATCH INTERNATIONAL; DRUG-FREE KIDS: AMERICA'S CHALLENGE, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether crude marijuana is a safe and effective medicine that should be available for medical purposes and be removed from Schedule I as a controlled dangerous substance?

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INTEREST OF AMICI AND SUMMARY OF ARGUMENT[1]

Amici are nonprofit corporations and individuals who are concerned with preventing drug abuse. The names of amici are: America Cares, Inc., Maryland; Arizonans for Drug-Free Youth and Communities, Arizona; CEDRO Centro de Informacion y Education para La Prevencion del Abuso de Drogas, Peru; Center for Drug Information, Illinois; Christian Drug Education Center, Colorado; Committees of Correspondence, Massachusetts; Community Anti-Drug Coalitions of America, Virginia; Concerned Citizens for Drug Prevention, Massachusetts; Drug Abuse Resistance Education (DARE), California; Drug Free America Foundation, Florida; Drug Free Kids: America's Challenge, Kentucky; Drug Prevention Network of the Americas, Texas; Drug Watch International, Nebraska; Drug Watch Minnesota, Minnesota; Educating Voices, Illinois; Hippokratic Society, Austria; Institute for Behavior and Health, Inc., Maryland; Institute on Global Drug Policy of the Drug Free America Foundation, Florida; International Drug Strategy Institute, Washington; International Scientific and Medical Forum on Drug Abuse, Florida; International Students in Action, California; Main South Alliance for Public Safety, Massachusetts; Maryland Alliance for Drug-Free Youth, Maryland; National Drug Prevention Alliance of the United Kingdom, United Kingdom; National Families in

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[1] The parties have consented to the filing of this brief. (See Appendix A.) Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *Amicus Curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

Action, Georgia; National Family Partnership, Florida; National Institute of Citizen Anti-Drug Policy, Virginia; National Coalition, Maryland; New Jersey Federation for Drug-Free Communities, New Jersey; Northwest Center for Health and Safety, Oregon; Parents Association to Neutralize Drug and Alcohol Abuse, Virginia; Positive Moves: Creating A Safe and Healthy World, Pennsylvania; PRIDE Omaha, Nebraska; S.O.S. Save Our Society From Drugs, Florida; Westminster Area Community Awareness Action Team, Colorado; Washington Drug-Free Business Initiative, Washington; Ernst Aeschbach, M.D., Switzerland; Mary Brett, England; Robert Dupont, M.D., former director, National Institute on Drug Abuse, Maryland; Drew Edwards, M.S., Florida; Stephanie Haynes, Texas; Janet Lapey, M.D., Massachusetts; Carla Lowe, California; Ambassador Mel Levitsky, former Assistant Secretary of State for International Narcotics Matters, New York; Ashraf Mozayani, Ph.D., Texas; Mina Seinfeld de Carakushansky, Ph.D., Drug Prevention Bureau of the City of Rio de Janeiro; Harold E. Shinitzky, Psy. D., Florida; Richard Schwartz, M.D., Virginia; and Raymond Scalettar, M.D., Washington D.C.

Amici are parents, parent and other drug-prevention organizations, and distinguished medical and scientific experts, policy makers, and others who all share a common concern that smoked or crude marijuana is disingenuously referred to as medicine. The international makeup of Amici reflects the international concern that illicit drug use is undercutting traditional values and threatening the very existence of stable families, communities, and government institutions throughout the world.

Amici collectively support families, communities, and nations that are free of illicit drug use, drug abuse, drug addiction, and drug-related deaths through advocacy and solid medical and scientific research and oppose the de jure and de facto legalization of marijuana and all other current illicit drugs. Smoked or "crude" marijuana is a dangerous Schedule I drug, notwithstanding creative attempts by those who seek its legalization to label its use as "compassionate" in medical settings. Lastly, medical marijuana initiatives now in law in eight states and the district of Columbia undermine national drug-enforcement priorities and our well-designed federal system of approval of new drugs. While future use of the state ballot initiative process as a tool to replace the legislative process must be dealt with by state legislatures, ultimately the federal government and courts must address this important issue to ensure a consistently applied and clearly understood national drug policy, as well as to preserve the Food and Drug Administration's medical and scientific new drug approval process that protects Americans from unsafe, ineffective drugs.

ARGUMENT

THE GOVERNMENT HAS A STRONG INTEREST IN PREVENTING THE DISTRIBUTION OF CRUDE MARIJUANA* UNDER CALIFORNIA'S PROPOSITION 215 WHICH VIOLATES FEDERAL LAW BECAUSE THE FOOD AND DRUG ADMINISTRATION HAS NOT APPROVED CRUDE MARIJUANA AS A SAFE OR EFFECTIVE MEDICINE AND IT IS A CONTROLLED SCHEDULE I DRUG

In *United States v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109 (9th Cir. 1999), the court reversed and remanded the District Court's decision granting the United States a preliminary injunction halting the distribution of crude marijuana for medical use by the Oakland Cannabis Buyers' Cooperative (the "OCBC") in the wake of Proposition 215, California's initiative legalizing medical use of crude marijuana. *Id.* at 1115. The District Court entered a preliminary injunction to stop the distribution of cannabis and held that the distribution of crude marijuana by certain cannabis clubs and their agents likely violated the Comprehensive Drug Abuse Prevention and

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* Throughout this brief we use the term "crude marijuana" to describe the illicit Schedule I drug that people abuse. The drug is derived from the leaves and flowering tops of the Cannabis plant and is consumed in a variety of ways. The dried plant material is most often rolled in paper and smoked as a cigarette, called a "joint." It is often placed in smoking devices called "bongs," smoked in pipes, or smoked in "blunts," which are cigars from which the tobacco has been removed and replaced with marijuana plant material. Sometimes it is baked in cookies or brownies and eaten, or brewed in tea and drunk. Other methods for consuming the drug are constantly being developed by the drug culture, including versions that allegedly aerosolize crude marijuana to remove its "tars."

Control Act of 1970 (the "Controlled Substances Act"), 21 U.S.C. § 841(a)(1). In reversing the District Court's decision, the Ninth Circuit stated that:

> In short, the OCBC had presented evidence that there is a class of people with serious medical conditions for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; who will suffer serious harm if they are denied cannabis; and for whom there is no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects.
>
> The government, by contrast, has yet to identify *any* interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes. *It has offered no evidence to rebut OCBC's evidence that cannabis is the only effective treatment for a large group of seriously ill individuals.* . . .

Id. at 1115 (emphasis added).

There is a strong governmental interest in prohibiting the distribution of crude marijuana as medicine. The federal government strives to protect our citizens from unsafe, ineffective substances sold as "medicines" and from drug abuse, drug addiction, and the abusive and criminal behaviors that marijuana and other illicit drugs often generate. The OCBC is distributing an unproven drug in disregard of the government's objective to ensure the safety and efficacy of medicines.

Because the OCBC is basing its right to procure and sell crude marijuana as "medicine," the drug must first be approved by the Food and Drug Administration (the "FDA"). The federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 351-360 gives the federal government sole responsibility for determining that drugs are safe and effective, a requirement all medicines must meet before they may be distributed to the public. The FDA has not approved marijuana as safe or effective, so the drug may not legally be prescribed and sold as a medicine. *See id.*

Not only has the FDA failed to approve marijuana, but marijuana is a Schedule I controlled substance under the Controlled Substances Act. Schedule I drugs have "1) a high potential for abuse, 2) no currently accepted treatment in the United States, and 3) a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(f).

In *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.D.C. 1994), the United States District Court for the District of Columbia accepted the Drug Enforcement Administration's new five-part test for determining whether a drug is in "currently accepted medical use." *Id.* at 1135. The test requires that:

(1) The drug's chemistry must be known and reproducible;

(2) there must be adequate safety studies;

(3) there must be adequate and well-controlled studies proving efficacy;

(4) the drug must be accepted by qualified experts; and

(5) the scientific evidence must be widely available.

Applying these criteria to a petition to reschedule crude marijuana, the court found that the drug had no currently accepted medical use and, therefore, had to remain in Schedule I. Thus, the OCBC disregarded the FDA's statutorily prescribed mandate created to ensure drug safety and is distributing an untested, unsafe Schedule I drug in violation of the Controlled Substances Act.

In reversing the District Court's decision, the Ninth Circuit also held that the District Court erred in failing to consider the criteria for a medical necessity exemption established by the Ninth Circuit in *United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir.1989). In *Aguilar* the court held that a defendant must establish the existence of four elements to be entitled to a necessity defense: (1) that he was faced with a choice of evils and chose the lesser evil; (2) that he acted to prevent imminent harm; (3) that he reasonably anticipated a causal relation between his conduct and the harm to be avoided; and (4) that there were no other legal alternatives to violating the law. *Id.* at 693.

The OCBC does not meet the *Aguilar* requirements because it fails to satisfy at least the first and fourth elements of the test. Although the FDA has not approved crude marijuana as safe and effective, the FDA *has* approved medications to treat all of the diseases, symptoms, and ailments named in Proposition 215. The OCBC is incorrect when it asserts that it was entitled to the necessity defense under *Aguilar* because it had no other legal alternatives to violating the law. Because safe and effective legal alternatives to crude marijuana exist, the OCBC can not satisfy the *Aguilar* test and, therefore,

cannot distribute marijuana as a medicine absent the approval of the FDA.

ADVOCATES HAVE TRIED TO LEGALIZE MARIJUANA IN ONE FORM OR ANOTHER FOR THREE DECADES

Drug-legalization advocates over the last three decades have employed a number of political and legal strategies to legalize marijuana. Between 1972 and 1978, the National Organization for the Reform of Marijuana Laws (NORML) successfully lobbied eleven state legislatures to "decriminalize" the drug, reducing penalties for possession in most cases to that of a traffic ticket. Also in 1972, NORML began the first of several unsuccessful attempts to petition the Drug Enforcement Administration (DEA) to reschedule marijuana from Schedule I to Schedule II on the grounds that crude marijuana had putative use in medicine. These attempts failed. See, *National Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654 (D.C. Cir. 1974); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin.*, 559 F.2d 735 (D.C. Cir. 1977); *National Org. for the Reform of Marijuana Laws v. Drug Enforcement Admin. & Dept. of Health, Education & Welfare*, No. 79-1660, 1980 U.S. App. LEXIS 13099 (D.C. Cir. Oct. 16, 1980); and *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

NORML and others led a second lobbying campaign aimed at states in the 1980s, this time to legalize crude marijuana as medicine. Some 35 states passed such laws but, because these laws were written by state legislative counsels and stayed within the framework of federal law, establishing statewide research programs under FDA

guidelines, advocates failed to get what they wanted – freely available marijuana.

In the early 1990s, NORML, the Drug Policy Foundation (DPF), and The Lindesmith Center (TLC) renewed the effort to legalize crude marijuana as medicine, this time using the state ballot initiative process, a process that allowed advocates to circumvent state legislative counsels and write their own laws. NORML, DPF, and TLC persuaded their most generous funders to create political organizations – Californians for Medical Rights and Arizonans for Drug Policy Reform – and to finance the first two medical marijuana initiatives in California and Arizona in 1996 and all subsequent initiatives that have passed since then. After the first two initiatives, Californians for Medical Rights became Americans for Medical Rights (AMR), which led successful medical marijuana initiative campaigns in 1998 in Alaska, Colorado, Nevada, Oregon, and Washington and in 1999 in Maine (Table 1). Different sponsors succeeded in passing a medical marijuana initiative in the District of Columbia 1998, with assistance from AMR.

Proposition 215, the state law under which the OCBC claims the right to obtain and sell cannabis, legalizes crude marijuana for "the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, *or any other illness for which marijuana provides relief*" (emphasis added). After the proposition passed, its author told the press that *anyone* who uses marijuana is "self-medicating" and that therefore *all* marijuana use is for medical purposes. "The Return of Pot", Hanna Rosin, *The New Republic*, February 17, 1997.

THE FACT THAT ONE CHEMICAL IN MARIJUANA IS AN FDA-APPROVED MEDICINE DOES NOT MAKE CRUDE MARIJUANA AN APPROVED MEDICINE

Crude marijuana is derived from the leaves and flowering tops of the Cannabis plant. It contains some 400 chemicals, most of which have not been studied by scientists. Some 60 of these chemicals, called cannabinoids, are unique to the Cannabis plant. One cannabinoid, Delta-9-tetrahydrocannabinol (THC), was synthesized, tested, and approved by FDA in 1985 for treating nausea in cancer patients and wasting in AIDS patients. The drug's generic name is dronabinol and its trade name is Marinol[R]. It is produced by Unimed Pharmaceuticals.

According to John A. Benson, Jr., M.D., of the Institute of Medicine, research on other cannabinoids is underway and some of these chemicals may one day prove to be useful medicines. However, he states:

> While we see a future in the development of chemically defined cannabinoid drugs, we see little future in smoked marijuana as a medicine.[2]

The fact that crude marijuana contains a chemical that has been synthesized, tested, and approved for medical use does not make marijuana itself a safe or effective medicine. Modern pharmaceutical science would require all the 400 or more chemicals in marijuana to pass the safety and efficacy tests in research, and this has not happened. Any consideration of this issue must take into account the substantial toxicity and morbidity associated

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[2] John A. Benson, Jr., Co-Principal Investigator, in releasing *Marijuana and Medicine: Assessing the Science Base*, Institute of Medicine, National Academy of Sciences, 1999.

with marijuana use. Because of the impurity of crude marijuana and its known toxic effects, it does not represent a useful medical alternative to currently available medications. Furthermore, efforts to gain legal status of marijuana through ballot initiatives seriously threaten the Food and Drug Administration process of proving safety and efficacy, and they create an atmosphere of medicine by popular vote, rather than the rigorous scientific and medical process that all medicines must undergo.

Before the development of modern pharmaceutical science, the field of medicine was fraught with potions and herbal remedies. Many of those were absolutely useless, or conversely were harmful to unsuspecting subjects. Thus evolved our current Food and Drug Administration and drug scheduling processes, which should not be undermined.

Having extensively reviewed available therapies for chemotherapy-associated nausea, glaucoma, multiple sclerosis, and appetite stimulation,[3] Drs. Voth and Schwartz have determined that no compelling need exists to make crude marijuana available as a medicine for physicians to prescribe. They concluded that the most appropriate direction for THC research is to research specific cannabinoids or synthetic analogs rather than pursuing the smoking of marijuana.

The conclusions of Drs. Voth and Schwartz were echoed a year later by the National Academy of Science's

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[3] Voth, E. A., Schwartz, R. H., Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana. *Annals of Internal Medicine*. 1997;126:791-798.

Institute of Medicine (herinafter "IOM Report") in an assessment of scientific marijuana and cannabinoid research (see below).[4]

Available research on the utility of THC has demonstrated some effectiveness of the purified form of the drug in treating nausea associated with cancer chemotherapy. Examples of such research include Sallan, et al.[5] who dealt only with pure THC in the treatment of chemotherapy-associated nausea, not smoked marijuana. Chang[6] tested THC and then followed treatment failures with marijuana, thus conclusions regarding effectiveness cannot be readily attributed to either THC or crude marijuana. Levitt[7] and coworkers actually determined that purified THC was more effective than smoked marijuana. Vinciguerra[8] found that smoked marijuana controlled

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[4] *Marijuana and Medicine: Assessing the Science Base.* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health. Institute of Medicine, National Academy of Sciences. National Academy Press, Washington D.C., 1999.

[5] Sallan, S. S., et al., Antiemetics effects of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy. *NEJM.* 1975;293:795-797.

[6] Chang, et al., Delta-9-tetrahydrocannabinol as an antiemetic in cancer patients receiving high-dose methotrexate. *Annals of Internal Medicine.* 1979;91:819-924.

[7] Levitt, et al., Randomized double blind comparison of delta-9-tetrahydrocannibinol and marijuana as chemotherapy antiemetics. *Proceedings of the Annual Meeting of the American Society of Clinical Oncology.* 1984:91.

[8] Vinciguerra, V., Moore, T., Brennan, E.: Inhalation marijuana as an antiemetic for cancer chemotherapy. *N.Y. State J. Med.* 1988; 88:525-527.

nausea in patients who had failed other conventional forms of antiemetic therapy. Responders tended to have had prior marijuana experience. This study was uncontrolled and patients self-evaluated results. Smokers were required to inhale deeply, hold the smoke for ten seconds, and then smoke four cigarettes completely each day of chemotherapy. Twenty-five percent refused to smoke the marijuana. Over 20% of the subjects dropped out of the smoking group prior to the end of the study and 22% of the remaining subjects reported no benefit from smoking marijuana. Dosing was also variable because of the fact that the dose was rounded to the nearest one-fourth marijuana cigarette, and no THC levels were checked for consistency of dose response.

Legalization advocates would have the public and policy makers incorrectly believe that crude marijuana is the only treatment alternative for masses of cancer sufferers who are going untreated for the nausea associated with chemotherapy, and for all those who suffer from glaucoma, multiple sclerosis, and other ailments. Numerous effective medications are, however, currently available for conditions such as nausea (Table 2).

In fact, the IOM report found that neither smoked marijuana nor cannabinoids are as effective as current medicines that stop nausea and vomiting in cancer chemotherapy patients. However, the scientists speculated that cannabinoids might be effective in those few patients who respond poorly to current antiemetic (anti-nausea) drugs or more effective in combination with current antiemetics. It recommended that research should be pursued for patients who do not respond completely to current

antiemetics and that a safe (non-smoking) delivery system *for cannabinoids should be developed.*

The negative side effect profile for marijuana, even oral dronabinol (Marinol[R]), far exceeds most of the other effective agents available. *If* there exist treatment failures of available medications in these patients, the use of marijuana would, at minimum, demonstrate unpleasant side effects. In the studies performed to examine THC for chemotherapy-associated nausea, elderly patients could not tolerate the drug. Chronic, daily doses of the drug would be necessary to treat many of the proposed medical conditions. This would unnecessarily expose the patients to the toxic effects.

Mattes[9] compared oral and rectal suppository preparations of THC with smoked marijuana. All study subjects were experienced marijuana users thus accounting for a relatively high drug acceptance. Smoked marijuana was no more effective than suppository THC in stimulating appetite as measured by caloric energy intake. Rectal suppositories and oral THC were dosed at 2.5 mg twice daily. Marijuana subjects were required to inhale for 3 seconds, hold the smoke deeply in their lungs for 12 seconds, and then continue the process until the cigarette was smoked to a stub. The plasma THC levels peaked more quickly with the inhaled THC, but also fell more quickly, whereas the suppository THC maintained a more sustained level.

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[9] Mattes, R. D., Engelman, K., Shaw, L. M., Elsohly, M. A., Cannabinoids and appetite stimulation. *Pharmacologic Pharmacology, Biochemistry, and Behavior.* 1994;49:187-195.

To examine the potential medical efficacy of marijuana as it relates to several disease states, a comprehensive review of the potential medicinal applications of marijuana was recently undertaken at the request of the Assistant Secretary of Health, Dr. Phillip Lee. Opinions were requested from investigators at the National Institute on Allergy and Infectious Diseases, who commented on the AIDS wasting syndrome; the National Cancer Institute who commented on the use of marijuana as an antiemetic in cancer chemotherapy; the National Eye Institute who commented on marijuana's use in glaucoma; and the National Institute for Neurological Disorders and Stroke who commented on marijuana's role as an antispasticity drug in multiple sclerosis. The summary opinion stated:

> This evaluation indicates that sound scientific studies supporting these claims are lacking despite anecdotal claims that smoked marijuana is beneficial. Scientists at the National Institutes of Health indicate that after carefully examining the existing preclinical and human data, there is no evidence to suggest that smoked marijuana might be superior to currently available therapies for glaucoma, weight loss associated with AIDS, nausea and vomiting associated with cancer chemotherapy, muscle spasticity associated with multiple sclerosis, or intractable pain.[10]

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[10] Lee, P. R., Letter to Congressman Dan Hamburg, United States Public Health Service, July 13, 1994.

The National Institutes of Health reconsidered this issue in 1997[11] and has called for further research into alternate delivery systems for pure THC as well as research into the comparative efficacy of marijuana with newer available medicines which have added heightened efficacy to medication regimes. The summary also called into attention concern over pulmonary, neuro-, and immuno-toxicity of cannabis.

In 1997 the White House Office of National Drug Control Policy commissioned the National Academy of Sciences Institute of Medicine (IOM) to undertake an evaluation of the utility of marijuana and other cannabinoids[12] for medicinal applications. The study concluded (Table 3) that the challenge for future research will be to find cannabinoids which enhance therapeutic benefits while minimizing side effects such as intoxication and dysphoria. Delivery systems such as nasal sprays, metered dose inhalers, transdermal patches, and suppositories could be useful delivery systems for isolated or synthetic cannabinoids. The future for medicinal applications of cannabinoids and whether cannabinoids are equal or superior to existing medicines remains to be determined, but the IOM evaluation is particularly clear on the smoking of marijuana:

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[11] Workshop on the Medical Utility of Marijuana. Report to the Director, National Institutes of Health. http://www.nih.gov/news/pr/aug97/nih-08.htm.

[12] *Marijuana and Medicine: Assessing the Science Base* Janet E. Joy, Stanley J. Watson, Jr., and John A. Benson, Jr., Editors. Division of Neuroscience and Behavioral Health, Institute of Medicine. National Academy Press, Washington, D.C. 1999. Internet address www.nap.edu.

> If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of a rapid-onset, non-smoked cannabinoid delivery system.[13]

The following excerpts from the IOM report are instructive:

> The goal for drugs that treat nausea and vomiting produced by cancer chemotherapy is complete control (stop vomiting completely) or major control (two or fewer episodes of vomiting). . . . [14] A controlled double-blind study compared THC with a standard antiemetic drug, metoclopramide, in cancer patients who received cisplatin, the chemotherapeutic drug that causes vomiting in more than 99 percent of patients. . . . [15]

Results	Complete Control	Major Control
Metoclopramide	47 percent	73 percent
THC	13 percent	27 percent

> (Other study) results suggest that THC reduces chemotherapy-induced emesis. These studies also indicate that the degree of efficacy is not

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[13] IOM Report, p. 20.

[14] Ibid., p. 4.11.

[15] Ibid., p. 4.11-4.12.

high. . . .[16] As with the THC trials, nabilone and levonantradol (two synthetic analogues of THC) reduced emesis, but not as well as other available agents. . . .[17] A double-blind, cross-over, placebo controlled study compared THC pills to smoked marijuana in 20 cancer patients receiving a variety of chemotherapeutic drugs. Only 25 percent of patients achieved complete control of vomiting. . . .[18]

Preferred THC Pills	35 percent
Preferred Marijuana	20 percent
No Preference	45 percent

Although many marijuana users have claimed that smoked marijuana is a more effective antiemetic than oral THC, no controlled studies have yet been published that analyze this in sufficient detail to estimate the extent to which that is the case. . . .[19] *Major progress, generally not well-known to the public, in controlling chemotherapy-induced acute nausea and vomiting has been made since the 1970s* (emphasis added). Patients receiving the most difficult to control emetic agents now have no more than a 20-30 percent likelihood of experiencing acute emesis, whereas in the 1970s the likelihood was nearly 100 percent despite (then standard) antiemetics. . . .[20] Cannabinoids are not as effective as several other classes of agents. . . . As with cannabinoids, efficacy was apparent with

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[16] Ibid., p. 4.12.

[17] Ibid., p. 4.13.

[18] Ibid., p. 4.13.

[19] Ibid., p. 4.14.

[20] Ibid., p. 4.15.

smoked marijuana, but the degree of efficacy was no better than that seen with available antiemetic agents now considered to be marginally satisfactory. It is theoretically possible . . . that added to more effective regimens, THC might enhance control of emesis. . . . The critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but rather whether there is a group of patients who might obtain added or better relief from marijuana or cannabinoid drugs. . . . [21] Most chemotherapy patients are unlikely to want to use marijuana or THC as an antiemetic. In 1998, there are more effective antiemetic agents available than were available earlier. By comparison, cannabinoids are only modest antiemetics. . . . However . . . cannabinoids might be effective in people who respond poorly to currently used antiemetic drugs, or cannabinoids might be more effective in combination with the new drugs than either are alone. . . . Therefore research should be pursued for patients whose nausea and vomiting is not completely controlled by standard antiemetics. . . . Antiemetic pills are given to cancer patients before chemotherapy begins and then afterwards. In those patients who nonetheless experience nausea and vomiting after chemotherapy, "an inhalation (but preferably not smoking) cannabinoid drug delivery system would be advantageous for treating chemotherapy-induced nausea."[22]

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[21] Ibid., p. 4. 16.

[22] Ibid., p. 4.17.

Marijuana adversely impacts concentration, motor coordination, and memory,[23] factors that must be considered in any discussion of providing this drug to patients suffering chronic diseases. The ability to perform complex tasks, such as flying,[24] is impaired even 24 hours after the acute intoxication phase. The association of marijuana use with trauma and intoxicated motor vehicle operation is also well established.[25] This is of central importance in an ambulatory environment where patients may smoke marijuana and then drive automobiles. Recent evaluations[26] of the effect of marijuana on driving determined that the combination of blood alcohol concentrations (BAC) of 0.07 and marijuana 100ug/kg gave effects similar to a BAC of 0.09. Blood alcohol concentrations of 0.07 and marijuana levels of 200ug/kg demonstrated effects similar to a BAC of 0.14 when measuring reaction time, on-road performance, and vehicle following. The study concluded, "Under marijuana's influence,

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[23] Murray, J. B., Marijuana's effects on human cognitive functions, psychomotor functions, and personality. *Journal of General Psychology.* 1986;113:23-55.

[24] Yesavage, J. A., Leirer, V. O., Denari, M., and Hollister, L. E., Carry-over effects of marijuana intoxication on aircraft pilot performance; a preliminary report. *Am. J. Psychiatry.* 1985;142:1325-1329.

[25] Gerostamoulos, J., and Drummer, O. H., Incidence of psychoactive cannabinoids in drivers killed in motor vehicle accidents. *Journal of Forensic Sciences.* 1993;38:649-656.

[26] National Highway Traffic Safety Administration. Marijuana and Alcohol Severely Impede Driving Performance. *Annals of Emergency Medicine* 2000:35;398-399. NHTSA study – National Highway Traffic Safety Administration. Marijuana Alcohol and Actual Driving Performance. DOT HS 808.939.

drivers have reduced capacity to avoid collisions if confronted with the sudden need for evasive action." A second related study found that a BAC of .05 combined with moderate marijuana produced a significant drop in the visual search frequency.

Positron scanning[27] of subjects' mean use of marijuana 17 times per week for the last 2 years found lower blood flow in a large region of the posterior cerebellum. Not only does this have implications on motor coordination and function, but also cognition, timing, processing sensory information, and attention.

Despite arguments of legalization advocates to the contrary, marijuana is a dependence-producing drug. Strangely, in the course of the rescheduling hearings, petitioners admitted that "marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence." These are points which they now deny. However, this dependence and associated "addictive" behaviors have been well described in the marijuana literature.[28] [29] [30]

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[27] Block, R. I., O'Leary, D. S., Hichwa, R. D., Augustinack, J. C., Boles-Ponto, L. L., Ghoneim, M. M., Arndt, S., Ehrhardt, J. C., Hurtig, R. H., Watkins, G. L., Hall, J. A., Nathan, P. E., Andreasen, N. C. Cerebellar hypoactivity in frequent marijuana users. *NeuroReport*. 2000;4:749-753.

[28] Compton, D. R., Dewey, W. L., and Martin, B. R., Cannabis dependence and tolerance production. *Advances in Alcohol and Substance Abuse*. 1990;9:129-147.

[29] Miller, N. S., and Gold, M. S., The diagnosis of marijuana (cannabis) dependence. *Journal of Substance Abuse Treatment*. 1989;6:183-192.

[30] Schwartz, R. H., Marijuana: an overview. *Pediatric clinics of North America*. 1987;34:305-317.

Marijuana dependence consists of both a physical dependence (tolerance and subsequent withdrawal) and a psychological dependence. Withdrawal from marijuana has been demonstrated in both animals[31] and humans.[32]

While the dependence producing properties of marijuana are probably a minimal issue for chemotherapy-associated nausea when medication is required sporadically, it is a major issue for the chronic daily use necessary for glaucoma, AIDS wasting syndrome, and other alleged chronic applications.

The respiratory difficulties associated with marijuana use preclude the inhaled route of administration as a medicine. Smoking marijuana is associated with higher concentrations of tar, carbon monoxide, and carcinogens than are found in cigarette smoking.[33] Marijuana adversely impairs some aspects of lung function and causes abnormalities in the respiratory cell lines from large airways to the alveoli.[34] [35] Marijuana smoke causes

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[31] Martin, B. R., The THC receptor and its antagonists. In: Nahas, G. G., Burks, T. F., eds. Drug Abuse in the Decade of the Brain. Amsterdam: IOS press. 1997:139-144.

[32] Duffy, A., Milin, R., Case Study: Withdrawal Syndrome in Adolescent Chronic Cannabis Users. *J. Am. Acad. Child Adolesc. Psychiatry.* 1996;35:1618-21.

[33] Wu, T. C., et al., Pulmonary hazards of smoking marijuana as compared with tobacco. *NEJM.* 1988;318:347-351.

[34] Tashkin, D. P., Shapiro, B. J., Lee, Y. E., and Harper, C. E., Subacute effects of heavy marijuana smoking on pulmonary function in healthy men. *NEJM.* 1976;294:125-129.

[35] Barbers, R. G., et al., Differential examination of bronchoalveolar lavage cells in tobacco cigarette and marijuana smokers. *Am. Rev. Respir. Dis.* 1987;135:1271.

inflammatory changes in the airways of young people that are similar to the effects of tobacco.[36] In addition to these cellular abnormalities and consequences, contaminants of marijuana smoke are known to include various pathogenic bacteria and fungi.[37] Those at particular risk for the development of disease and infection when these substances are inhaled are those users with impaired immunity.

One of the earliest findings in marijuana research was the effect on various immune functions, which is now evidenced by an inability to fight herpes infections and the discovery of a blunted response to therapy for genital warts during cannabis consumption.[38]

Abnormal immune function is, of course, the cornerstone of problems associated with AIDS. The use of chronic THC in smoked form for AIDS wasting not only exposes the patient to unnecessary pathogens, but also risks further immunosuppression. Evaluation of the effect of THC on NK-*k*B has suggested a possible effect on the HIV genome. A hallmark of the treatment for AIDS is *avoidance* of drug use, not extension or perpetuation of it.

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[36] Roth, M. D., Arora, A., Barsky, S. H., Kleerup, E. C., Simmons, M., Tashkin, D. P., Airway inflammation in young marijuana and tobacco smokers. *Am. J. Respir. Crit. Care Med.* 1998;157:928-937.

[37] Fleisher, M., Winawer, S. J., and Zauber, A. G., Aspergillosis and marijuana. *Annals of Internal Medicine.* 1991;115:578-579.

[38] Gross, G., Roussaki, A., Ikenberg, Drees N., Genital warts do not respond to systemic recombinant interferon alfa-2 treatment during cannabis consumption. *Dermatologica.* 1991; 183:203-207.

It should be clear that marijuana exposes the user to substantial health risks. In chronic use, or use in populations at high risk for infection and immune suppression, the risks are unacceptable.

Amici assert that in the interest of protecting seriously and terminally ill patients from unsafe and ineffective drugs, the safety and efficacy process of the FDA cannot be bypassed. Crude marijuana, an impure and toxic substance has no place in the medical armamentarium. It is no more reasonable to consider marijuana a medicine than it is to consider tobacco a medicine.

Coupled with the medical risk to patients, serious regulatory questions arise that have not been adequately dealt with by ballot initiatives. Those who propose medical uses, or who conduct research on the use of marijuana, have an ethical responsibility not to expose their subjects to unnecessary risks. Under current guidelines, crude marijuana is not a medicine, and allowing it as such would be a step backward to the times of potions and herbal remedies.

DIMINISHING PERCEPTION OF HARM INCREASES USE

Amici note the profound correlation in benchmark surveys of drug use, which show that the more people who believe a drug is harmful, the fewer people use that drug. Equally profound are the surveys' findings that the reverse is also true: the fewer people who believe a drug is harmful, the more people use that drug. These surveys show that perception of harm with respect to marijuana has been dropping off annually since the renewal of the

drive to legalize marijuana as medicine, which began in the early 1990s when legalization advocates first gained a significant increase in funding and began planning the state ballot initiative drive to legalize crude marijuana as medicine. The surveys are the Monitoring the Future Survey, which has tracked drug use among American high school students annually since 1975[39] and the National Household Survey on Drug Abuse, which has tracked drug use among Americans ages 12 and older annually or less frequently since 1972.[40]

The 1999 National Household Survey on Drug Abuse, released in October 2000, was conducted for SAMHSA by North Carolina's Research Triangle Institute.[41] For the first time in the history of this survey, the population sample was vastly increased (from an average of 15,000 to 75,000) in order to provide data about individual states, as well as about the nation as a whole. The state data reveals that those states which have passed medical marijuana laws have among the highest levels of past-month marijuana use, of past-month other drug use, of drug addiction, and of drug and alcohol addiction (Also see Table 4):

> **Drug Addiction** – Alaska and Nevada have the highest rates of drug addiction in the nation,

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[39] *Monitoring the Future*, National Institutes of Health, National Institute on Drug Abuse, available on the Internet at <www.monitoringthefuture.org>.

[40] *Summary of Findings from the 1999 National Household Survey on Drug Abuse*, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Rockville MD, 2000, pp 64-65, 74-75.

[41] Ibid.

California and Oregon have the 4th highest rates, the District of Columbia has the 5th highest rate, Washington has the 6th highest rate, Arizona and Colorado have the 7th highest rates, and Maine has the 12th highest rate.[42]

Drug Use – Alaska has the highest rate of past-month drug use in the nation, Nevada has the 3rd highest rate, Colorado has the 4th highest rate, Washington has the 8th highest rate, California has the 9th highest rate, Oregon has the 11th highest rate, the District of Columbia has the 12th highest rate, and Arizona and Maine have the 15th highest rate.[43]

Amici are concerned about protecting seriously and terminally ill patients from being exposed to an unapproved drug. In contrast, we have *no* objection to any medicines that may evolve from the cannabinoids, including Marinol, provided that they are approved as safe and effective by the Food and Drug Administration under current federal law.

Amici are also concerned that legalization advocates' efforts to confuse the public about the difference between crude marijuana and the cannabinoids that scientists are studying for possible use in medicine have contributed to the past decade's drop in the perception of marijuana's harm and that this has resulted in an increase in marijuana use, other drug use, and drug addiction.

Amici believe that it is therefore critically important that the Supreme Court uphold the supremacy of the

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[42] Ibid.

[43] Ibid.

federal FDA new drug approval laws and of the federal Controlled Substance Act and strike down California's Proposition 215 and the other state medical marijuana laws that violate these federal statutes.

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APPENDIX

TABLE 1

States That Have Passed Medical Marijuana Initiatives[44]

California
Proposition 21
The Compassionate Use Act of 1996

Arizona
Proposition 200
The Drug Medicalization, Prevention, and Control Act of 1996

Proposition 300
A 1998 initiative to reinstate certain provisions of Proposition 200

Alaska
A 1998 Act Relating to the Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions
Passed in 1998, but invalidated by the Colorado Supreme Court for insufficient signatures.

Nevada
Medical Marijuana Initiative of 1998

Oregon
Oregon Medical Marijuana Act of 1998

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[44] National Families in Action A Guide To Drug-Related State Ballot Initiatives, Initiative-Index, www.national families.org/guide/initiative__index.html.

Washington
Initiative 692
Medical Use of Marijuana Act of 1998

District of Columbia
Initiative 59
Legalization of Marijuana for Medical Treatment Initiative of 1998
Different sponsors but assisted by Americans for Medical Rights

Maine
A 1999 Act to Permit the Medical Use of Marijuana

Colorado
Medical Use of Marijuana for Persons Suffering from Debilitating Medical Conditions Passed in 2000.

Nevada
Medical Marijuana Initiative of 2000
Second vote required to amend state constitution

TABLE 2

EXAMPLES OF NON-CANNABINOID MEDICATIONS AVAILABLE FOR NAUSEA ASSOCIATED WITH CANCER CHEMOTHERAPY

Serotonin Antagonists
- Ondansetron (Zofran)
- Granisetron (Kytril)
- Tropisetron (Navoban)
- Dolasetron

Phenothiazines:
- Prochlorperazine (Compazine)
- Chlorpromazine (Thorazine)
- Thiethylperazine (Torecan)
- Perphenazine (Trilafon)
- Promethazine (Phenergan)

Corticosteroids
Dexamethasone (Decadron)
Methylprednisolone (Medrol)

Anticholinergics
Scopolamine (Trans Derm Scop)

Butyrophenones
Droperidol (Inapsine)
Haloperidol (Haldol)
Domperidone (Motilium)

Benzodiazepines
Lorazepam (Ativan)
Alprazolam (Xanax)

Substituted Benzamides
Metoclopramide (Reglan)
Trimethobenzamide (Tigan)
Alizapride (Plitican)
Cisapride (Propulsid)

Antihistamines
Diphenhydramine (Benedryl)

TABLE 3

Institute of Medicine Recommendations[45]

Recommendation 1: Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body. Because different cannabinoids appear to have different effects, cannabinoid research should include, but not be restricted to, effects attributable to THC alone.

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[45] IOM Report, p. ES. 11.

Recommendation 2: Clinical trials of cannabinoid drugs for symptom management should be conducted with the goal of developing rapid-onset, reliable, and safe delivery systems.

Recommendation 3: Psychological effects of cannabinoids such as anxiety reduction and sedation, which can influence perceived medical benefits, should be evaluated in clinical trials.

Recommendation 4: Studies to define the individual health risks of smoking marijuana should be conducted, particularly among populations in which marijuana use is prevalent.

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.

Recommendation 6: Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:

- failure of all approved medications to provide relief has been documented,
- the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs,
- such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and

– involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

Note: Recommendations 5 and 6 are consistent with current FDA research guidelines. The IOM report cautions that "the purpose of clinical trials of smoked marijuana," using research-grade marijuana rather than street marijuana, "*would not be to develop marijuana as a licensed drug,* but such trials could be a first step towards the development of a rapid-onset, nonsmoked cannabinoid delivery system" (emphasis added.) See our footnote 13.

TABLE 4

1999 National Household Survey on Drug Abuse[46]

(Highlighted states have passed medical marijuana initiatives since 1996)

Percent Reporting Past-Year Drug Dependence

State	Ranking	Rate
Alaska	**1**	**2.8**
Nevada	**1**	**2.8**
New Mexico	2	2.7
Delaware	3	2.4
California	**4**	**2.3**
Oregon	**4**	**2.3**
District of Columbia	**5**	**2.2**
Washington	**6**	**2.1**
Rhode Island	6	2.1
Massachusetts	6	2.1
Arizona	**7**	**2.0**
Colorado	**7**	**2.0**
Utah	7	2.0
Vermont	7	2.0
Connecticut	8	1.9
Montana	8	1.9
Michigan	9	1.8
New Hampshire	9	1.8
New York	9	1.8
National Average		1.7
Kansas	10	1.7
Louisiana	10	1.7
Minnesota	10	1.7
Mississippi	10	1.7
New Jersey	10	1.7

Percent Reporting Past-Month Drug Use

State	Ranking	Rate
Alaska	**1**	**10.7**
Massachusetts	2	10.1
Nevada	**3**	**9.6**
Colorado	**4**	**9.3**
New Mexico	5	8.9
Rhode Island	6	8.7
Delaware	7	8.5
Washington	**8**	**8.4**
California	**9**	**8.3**
Michigan	10	8.0
Oregon	**11**	**7.7**
Montana	11	7.7
New Jersey	11	7.7
Connecticut	11	7.7
District of Columbia	**12**	**7.6**
Indiana	13	7.5
Wyoming	14	7.3
Arizona	**15**	**7.1**
Maine	**15**	**7.1**
Hawaii	15	7.1
New/ Hampshire	16	7.0
New York	16	7.0
Pennsylvania	16	7.0
Wisconsin	16	7.0
National Average		6.9

Wyoming	10	1.7
Illinois	11	1.6
Indiana	11	1.6
Maryland	11	1.6
Missouri	11	1.6
Ohio	11	1.6
Wisconsin	11	1.6
Maine	**12**	**1.5**
Idaho	12	1.5
Georgia	12	1.5
North Carolina	12	1.5
North Dakota	12	1.5
Oklahoma	12	1.5
Pennsylvania	12	1.5
Tennessee	12	1.5
Alabama	13	1.4
Arkansas	13	1.4
Hawaii	13	1.4
Nebraska	13	1.4
South Carolina	13	1.4
South Dakota	13	1.4
Texas	13	1.4
Florida	14	1.3
Kentucky	14	1.3
Virginia	15	1.3
Iowa	16	1.2
West Virginia	16	1.2
Illinois	17	6.9
Florida	18	6.8
Vermont	18	6.8
Minnesota	19	6.7
Missouri	20	6.6
Ohio	21	6.5
Idaho	22	6.4
North Carolina	23	6.3
Utah	24	6.2
Kentucky	25	6.0
South Dakota	25	6.0
Kansas	26	5.9
Georgia	27	5.8
Mississippi	27	5.8
Louisiana	28	5.7
Nebraska	29	5.6
Iowa	30	5.5
Tennessee	30	5.5
North Dakota	31	5.4
South Carolina	31	5.4
Texas	31	5.4
Maryland	32	5.3
Alabama	33	5.1
Oklahoma	33	5.1
West Virginia	33	5.1
Arkansas	34	5.0
Virginia	35	4.7

[46] National Families in Action: A Guide To Drug-Related State Ballot Initiatives, Percentage Reporting Past-Year Dependence, www. nationalfamilies.org/guide/dependence_use.html.

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In the

Supreme Court of the United States

October Term, 2000

UNITED STATES OF AMERICA;

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, *et al.*,

Respondents.

On Writ of *Certiorari* to the
United States Court of Appeals for the Ninth Circuit

BRIEF OF FAMILY RESEARCH COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS*

Family Research Council, Inc. (hereinafter "FRC")[1] is a non-profit, research and educational organization dedicated to articulating and advancing a family-centered philosophy of public life. In addition to providing policy research and analysis for the legislative, executive, and judicial branches of the federal government, FRC seeks to inform the news media, the academic community, business leaders, and the general public about family issues that affect the nation.

FRC's legal and public policy experts are continually sought out by federal and state legislators for assistance and advice. FRC has participated in numerous *amicus curiae* briefs in the United States Supreme Court, lower federal courts, and state courts.

Lieutenant Colonel Robert L. Maginnis, USA Retired, is FRC's Vice President of National Security and Foreign Policy. He is a respected anti-drug expert having spoken at conferences in the United States and abroad. His anti-drug insights are sought by the media, grassroots activists, and government officials. In October 1999, Senator Trent Lott appointed Colonel Maginnis to the National Parents Advisory Council on Drug Abuse. Col. Maginnis has written and spoken extensively on the subject of the decriminalization of drugs and the use of marijuana for medicinal purposes. He has spoken to the following organizations on the subject of medical marijuana: Conference on why South Africa should not legalize drugs, Pratoria, South Africa, July 27-28, 2000; Illinois Police Chiefs Association, January 22, 2000; the U.S. House of

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[1] In accordance with Rule 37 of the Rules of this Court, the *amicus curiae* submit this brief in support of petitioner. All parties have consented to the submission of this brief in its entirety, and no other person or entity, besides *amicus curiae*, has made a monetary contribution to the preparation of this brief.

Representatives Subcommittee on Criminal Justice, Drug Policy, and Human Resources, "The Pros and Cons of Drug Legalization, Decriminalization and Harm Reduction," June 16, 1999; the U.S. House of Representatives Subcommittee on Crime, the Judiciary Committee, on Drug Enforcement Administration, citing FRC drug policy polling results, July 29, 1999; the Illinois Drug Education Alliance in November 1997, 1998 and 1999; the Rainbow International Association Against Drugs, San Patrignano, Rimini, Italy, October 4, 1997; Virginia House of Delegates committee concerning "medical" marijuana on January 21, 1997; conducted and published a national voter survey "America Assesses 'Medical' Marijuana" in 1997; conducted and published national voter polling on drug policy which included questions about "medical" marijuana in 1998. Col. Maginnis's writings, some of which are included herein, will be beneficial to the Court in deciding this matter.

SUMMARY OF ARGUMENT

A medical necessity exemption for marijuana is unnecessary and the harm will outweigh any benefits. The principal active ingredient in marijuana, delta-9-tetrahydrocannabinol (THC), is available in a prescribable pill called Marinol; it is also available as a rectal suppository that allows patients to absorb THC faster than Marinol or smoking crude marijuana. THC, however, is a mind-altering and dangerous substance. THC affects cognition, memory, pain perception and motor coordination. It produces euphoria and relaxation but also can deliver anxiety and panic reactions. The user's heart rate is severely elevated for up to three hours.

Crude marijuana is bad medicine that harms the brain, heart, and lungs; it limits learning, memory, perception, judgment and complex motor skills. While the evidence supports the selective use of pure THC to treat nausea associated cancer chemotherapy and to stimulate

appetite, the evidence does not support the reclassification [to Schedule II, a prescribable drug] of crude marijuana. The delivery system is unhealthful and unreliable. Marijuana smoke increases the risks for cancer, lung damage, and problems with pregnancies, including low birth weight. In addition, plants contain a variable mixture of biologically-active compounds and cannot be expected to provide a precisely defined drug effect.

Pro-marijuana arguments heavily rely on anecdotal evidence instead of controlled studies. Many people make the claim that marijuana use has helped control aspects of various diseases. Marijuana is addictive and addicts tend to feel better when they receive their drug.

Permitting "medicalization" of crude marijuana would result in many negative consequences that the federal drug laws are designed to prevent. Medicalization changes society's (particularly children's) attitudes toward the perceived dangerousness of illicit drug use. In California and Arizona, two states that have legalized marijuana for medical use, the number of current drug users of all ages was higher in California (8.3 percent) and Arizona (8.4 percent) than in the remainder of the United States (6.1 percent). Medicalization, particularly of the type practiced in California, makes marijuana much more available for illicit use. A California appeals court found that a marijuana dispensary operating in San Francisco "generally demonstrate[d] an indiscriminate and uncontrolled pattern of sale to thousands of persons among the general public, including persons who had not demonstrated any recommendation or approval of a physician and, in fact, some of whom were not under the care of a physician, such as undercover officers. Young children were seen wandering in and out of the premises, and some persons who had purchased marijuana on respondents' premises were reselling it unlawfully on the street. The declarations also reveal that respondents were importing marijuana, in violation of section 11360(a)."

There is a high correlation between marijuana use and many social and public health harms. Studies find that a high percentage of reckless drivers and accident victims used marijuana. A study testing urine samples of reckless drivers who were not obviously drunk from alcohol found that 59 percent of the drivers tested positive for cocaine and marijuana. Another study of more than 1,000 accident victims found that 35 percent had detectable levels of marijuana in their blood. In 1998, the Arrestee Drug Abuse Monitoring program found that "among juvenile arrestees, marijuana is overwhelmingly the primary drug of use." Positive rates for marijuana among male juvenile arrestees ranged from 64 percent in Phoenix to 35 percent in San Jose. In 1996, of all jail inmates, 78.2 percent had used marijuana at some point. More than half (54.9 percent) had been regular marijuana users. One-third (36.8 percent) used marijuana in the month before the offense and 18.5 percent used marijuana at the time of the offense. Marijuana is linked to 20.5 percent of cases involving child maltreatment. According to a 1990 article in the *Journal of the American Medical Association*, marijuana users caused 55 percent more industrial accidents than non-users, and had 85 percent more injuries at work than non-users.

Past periods of legalization of marijuana have produced negative consequences. Dutch tolerance of drug use has created a climate that drug manufacturers and traffickers have seized upon to produce and market more addictive and dangerous drugs. This has led to the Netherlands becoming a major producer of illicit synthetic drugs.

Medicalization of marijuana is a pretense used by many advocates of legalization. An April 1999 article in *Proceedings of the Association of American Physicians* states, "Most supporters of smoked marijuana are hostile to the use of purified chemicals from marijuana, insisting that only smoked marijuana leaves be used as 'medicine,' revealing clearly that their motivation is not scientific medicine but

the back door legalization of marijuana." In 1999, Barry McCaffrey, director of the Office of National Drug Control Policy, warned a congressional committee of "a carefully camouflaged, well-funded, tightly knit core of people whose goal is to legalize drug use in the United States."

ARGUMENT

I. A MEDICAL NECESSITY EXEMPTION FOR MARIJUANA IS UNNECESSARY AND THE HARM WILL OUTWEIGH ANY BENEFITS.

A. THC, the principal active ingredient in marijuana, is available in a refined pill form without the additional harmful effects of crude marijuana.

The principal active ingredient in marijuana, delta-9-tetrahydrocannabinol (THC), is available in a prescribable pill called Marinol®. Marinol® (dronabinol) was first approved in 1985 for the treatment of the nausea and vomiting associated with chemotherapy in patients who have failed to respond adequately to conventional antiemetic (anti-nausea) treatments. In 1992, the FDA approved a supplemental new drug application for Marinol® treatment of appetite loss or anorexia associated with weight loss in patients with AIDS.[2]

A May 1997 review of 6,059 titles in the *Annals of Internal Medicine* focused on the medical use of THC derivatives for nausea associated with chemotherapy, glaucoma, stimulation of appetite, and spinal cord spasticity. The authors state that the evidence supports the selective use of <u>pure</u> THC to treat nausea associated cancer

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[2] Marinol® (dronabinol) Drug History, Roxane Laboratories, Inc., P.O. Box 16532, Columbus, Ohio, undated.

chemotherapy and to stimulate appetite. The evidence does not support the reclassification [to Schedule II, a prescribable drug] of crude marijuana.[3]

In addition to the THC pill, researchers developed a rectal suppository that would allow patients to absorb THC faster than by Marinol or smoking crude marijuana.[4]

B. THC has its own negative side effects that prevent it from being the drug of choice for the vast majority of patients.

THC, the purified and tested form of the principal active ingredient in marijuana, is not well received because of its serious side effects. Dr. Eric A. Voth, is an assistant professor of medicine at the University of Kansas and chairman of the Institute on Global Drug Policy who has treated drug addicts for 10 years, and testified at a congressional hearing on the legalization of marijuana. Voth asserts, "The negative side-effect profile for marijuana, even dronabinol (Marinol), far exceeds most of the other effective agents available."[5] Voth backs this assertion by citing a study that ranked non-inhalant THC as only sixth in preference among oncologists for the treatment of severe nausea, and only ninth for mild nausea.[6]

THC is a mind-altering and dangerous substance. THC affects cognition, memory, pain perception and motor

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[3] Eric A. Voth, M.D. and Richard H. Schwartz, *Medicinal Applications of Delta-9-Tetrahydrocannabinol and Marijuana,* 126 Annals of Internal Med. 791 (1997).

[4] Sheila Hardwell Byrd, *Marijuana Project Develops New Treatment; Suppositories Option for Pain Management,* The Commercial Appeal, Feb. 27, 2000, at D6.

[5] *Crude Marijuana as a Medicine, Hearings on Marijuana Use in America. Before the Subcommittee on Crime of the House Judiciary Committee,* 105th Cong., 2nd Sess. 7 (statement of Eric A. Voth, M.D.).

[6] *Id.* at 6.

coordination. It produces euphoria and relaxation but also can deliver anxiety and panic reactions. The user's heart rate is severely elevated for up to three hours.[7]

The June 1997 issue of *Science* profiles two studies that demonstrate similarities between marijuana's effects (cased by THC) on the brain and those produced by highly addictive drugs such as cocaine, heroin, alcohol, and nicotine. Marijuana manipulates the brain's stress and reward systems in the same way as heroin and cocaine. One of the researchers said, "I would be satisfied if, following all this evidence, people would no longer consider THC a 'soft' drug."[8] Dr. Alan I. Leshner, director of the National Institute of Drug Abuse, commented on the study: "We know that a substantial number of chronic marijuana users become addicted, and previous research with animals has shown that stopping heavy marijuana use suddenly can cause distinct withdrawal symptoms."[9]

The psychoactive properties of marijuana may trigger latent psychopathology of many types. In some people, chronic marijuana use can produce an acute psychosis in which confusion, amnesia, delusions, hallucinations, anxiety, agitation and hypomanic symptoms predominate.[10]

The July 2000 issue of the *Journal of Immunology* states that THC can promote tumor growth by impairing the body's anti-tumor immunity system.[11]

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[7] Wayne Hall and Nadia Solowij, *Adverse Effects of Cannabis*, 352 The Lancet 1611, 1612 (1998) [hereinafter *Cannabis*].

[8] Ingrid Wickelgren, *Marijuana: Harder Than Thought?* 276 Science 1967, 1968 (1997).

[9] *Id.*

[10] Division of Neuroscience and Behavioral Health, Institute of Medicine, *Marijuana as Medicine: Assessing the Science Base* 3.29 (1999) [hereinafter *Marijuana*].

[11] Li X. Zhu, *Delta-9 Tetrahydrocannabinol Inhibits Antitumor Immunity By a cb2 Receptor-Mediated, Cytokine-Dependent Pathway*, 165 The J. of Immunology 373, 377 (2000).

In 1999, the Institute for Medicine (IOM), an independent non-profit organization released a review commissioned by the Office of National Drug Control Policy of the scientific studies of marijuana's medical worth. The review found "The effect of cannabinoids on the symptoms studied are generally modest, and in most cases, there are more effective medications."[12]

II. CRUDE MARIJUANA IS BAD MEDICINE.

The federal government classifies marijuana as Schedule I drug (21 U.S.C. § 812), meaning it is unable to be prescribed, has a high potential for abuse, is not currently accepted for medicinal use, and has a lack of safety.

Donna Shalala, Secretary of Health and Human Services, has said: "There is clear scientific evidence that marijuana is harmful to one's brain, heart, and lungs. It limits learning, memory, perception, judgment and complex motor skills like those needed to drive a vehicle. It has been shown to damage motivation and interest in one's goals and activities. It can cause chronic coughing and bronchitis. In short, it is a very dangerous drug."[13]

A. The delivery system is unhealthful and unreliable.

In the November 1996 elections, California and Arizona voters passed referenda in their states that legalized the use of marijuana as a medicine. In response, the Office of National Drug Control Policy commissioned the Institute of Medicine (IOM), an independent nonprofit organization in Washington, D.C., to review all the relevant scientific

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[12] *Marijuana, supra* note 10, at 4.

[13] *Marijuana and Tobacco Use Still Rising Among 8th and 10th Graders*, HHS News, (U.S. Dep't of Health and Human Serv., Wash., D.C.), Dec. 19, 1996.

studies of marijuana's medicinal worth. The review was not designed to address policy recommendations. In March 1999, the IOM researchers presented their findings in a book titled *Marijuana and Medicine: Assessing the Science Base*:

> Although marijuana smoke delivers THC and other cannabinoids to the body, it also delivers harmful substances, including most found in tobacco smoke. In addition, plants contain a variable mixture of biologically-active compounds and cannot be expected to provide a precisely defined drug effect. For those reasons, the report concludes that the future of cannabinoid drugs lies not in smoked marijuana, but in chemically defined drugs that act on the cannabinoid systems that are a natural component of human physiology.[14]

The 1999 IOM study concluded "[d]efined substances, such as purified cannabinoid compounds, are preferable to plant products which are of variable and uncertain composition . . . ."[15] Cannabis contains more than 400 chemicals, some of which are known to be carcinogenic.[16]

Dr. John A. Benson, Jr., one of the two researchers at IOM, and co-author of *Marijuana and Medicine* has described the medical risks of smoking marijuana:

> Marijuana's potential as medicine is seriously undermined by the fact that people smoke it, thereby increasing their chance for cancer, lung damage, and problems with pregnancies, including low birth weight. For that reason, we do not recommend smoking marijuana for long-term medical use. While we see a future in the development of

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[14] *Marijuana, supra* note 10, Preface.

[15] *Id.* at 4.

[16] Nat'l Inst. on Drug Abuse, U.S. Dep't of Health and Human Services., *Marijuana: Facts Parents Need to Know NIH Publication No. 95-4036* 5 (1995).

> chemically defined cannabinoid drugs, we see little future in smoked marijuana as a medicine.[17]

Dr. Stanley J. Watson, Jr., a researcher on medical marijuana at the IOM and co-author *Marijuana and Medicine*, has also rejected smoking marijuana for medicinal benefits:

> Although the issue of whether or not to permit patients to smoke marijuana is an important one, we believe it is really only a short-term consideration. Marijuana's future as medicine does not involve smoking. It involves exploiting the potential in cannabinoids such as THC, the key psychoactive ingredient of marijuana.[18]

A by-product of smoking crude marijuana is that it increases the patient's chances of lung cancer. One study found that marijuana smoking resulted in up to four times the respiratory burden of an equivalent amount of tobacco smoking.[19] Dr. Donald Tashkin, a lung specialist at the University of California, found that smoking marijuana damages the trachea and bronchial tubes in ways that may lead to lung cancer, and that marijuana smokers who inhale three or four joints a day suffer from chronic bronchitis as often as cigarette smokers who smoke four times as many cigarettes a day or more.[20] A September, 1993, National Institute on Drug Abuse update reported, "Daily use of one to three marijuana joints appears to produce approximately the same lung damage and potential cancer risk as smoking five times as many cigarettes."[21]

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[17] Dr. John A. Benson, Jr., Opening Statement, Press Conference Introducing *Marijuana and Medicine: Assessing the Science Base* (Mar. 17, 1999).

[18] *Id.*

[19] Tzu-Chin Wu, et al., *Pulmonary Hazards of Smoking Marijuana as Compared with Tobacco* 318 New Eng. J. of Med. 347, 349 (1988).

[20] Eric Risberg, *Blowing the Lid Off Pot*, Chicago Sun-Times, Jan. 19, 1997, at 34.

[21] *Marijuana Update*, NIDA Capsules (Nat'l Inst. on Drug Abuse, Nat'l Inst. Of Health, Rockville, Md.), Sept. 1994, at 2.

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The August 1998 issue of *The Journal of the National Cancer Institute* reported on a study that found long-term marijuana smoking might increase the risk of lung cancer. The study compared respiratory tract tissue samples from 28 healthy volunteers and 76 smokers of tobacco, marijuana and cocaine. The researchers concluded that smoking anything increased the cancer risk.[22]

Marijuana deposits four times as much tar in the lungs as does tobacco.[23] Marijuana smokers are less able to destroy fungal and bacterial organisms, as well as tumor cells.[24]

The November 1998 issue of *The Lancet*, British medical journal, included a review article titled "Adverse Effects of Cannabis." The article reveals that the typical cannabis (marijuana) cigarette is highly unpredictable in terms of THC dose delivery. Not only does it radically vary in terms of THC content, but the bioavailability of THC ranges from 5 to 24 percent.[25] The average THC content of commerical-grade marijuana is 5.57 percent, but can range as high as 25 to 30 percent, making accurate dosing nearly impossible.[26]

A November 1999 article in *The Lancet* found that inhalation of marijuana does lower eye pressure. However, the amount of marijuana smoke needed to produce clinical benefits may be associated with substantial side effects.[27]

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[22] *Smoking Drugs Linked to Cancer*, The Wash. Post, Aug. 19, 1998, at A8.

[23] *Marijuana, supra* note 10, at 3.35.

[24] *Id.* at 3.36.

[25] *Cannabis, supra* note 7.

[26] Office of Nat'l Drug Control Policy, Executive Office of the President, *National Drug Control Strategy, 2000 Annual Report* 13 (2000) [hereinafter *National*]; Gary Fields, *Potent Marijuana Strain Invigorates Drug Trade*, USA Today, Jan. 13, 1999, at 3A.

[27] Anne L. Coleman, *Glaucoma*, 354 The Lancet 1803, 1806-07 (1999).

A November 1998 review article in *Archives of Ophthalmology* concludes that smoking marijuana causes a fall in intraocular pressure (IOP) in 60 percent to 65 percent of users, but it cautions that continued use at a rate needed to control glaucomatous IOP would lead to substantial systemic toxic effects.[28]

An October 1998 study in *The New England Journal of Medicine* confirms that previous science discovered marijuana smoking can reduce IOP, but it has side effects like alterations in mental status. The authors conclude "that a deleterious effect on optic-nerve blood flow, resulting from systemic hypotension [the result of smoking marijuana] might offset any benefit of reduced intraocular pressure."[29]

A 1994 study published in *Clinical Pharmacology & Therapeutics* found that a single marijuana cigarette increased postural tracking error, decreased response speed and further impaired posture and balance. The authors concluded that marijuana smoking impairs coordination and balance in patients with spastic MS.[30]

The National Institute on Allergy and Infectious Diseases has identified two commercially available treatments for anorexia/cachexia in patients with AIDS, Megace (magastrol acetate) and Marinol. The Institute dismisses marijuana as an effective AIDS wasting drug by identifying four limitations: drug absorption via smoking may be "impractical or unacceptable;" marijuana includes "a complex mixture of over 400 compounds including

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[28] Keith Green, *Marijuana Smoking vs. Cannabinoids for Glaucoma Therapy*, 116 Archives of Ophthalmology 1433 (1998) available at http://www.ama-assn.org/sci-pubs/j...ost/recent/issues/opht/ecs8385.htm.

[29] Wallace L. M. Alward, *Medical Management of Glaucoma*, 339 The New Eng. J. of Med. 1298, 1305 (1998).

[30] Harry S. Greenberg, *Short-term Effects of Smoking Marijuana on Balance in Patients With Multiple Sclerosis and Normal Volunteers*, 55 Clinical Pharmacology & Therapeutics 324, 329 (1994).

polyaeromatic hydrocarbons which are carcinogenic;" marijuana is often contaminated with salmonella and fungal spores which compromise the immune system; and the mind altering effect may distress patients.[31]

In July 1998, *Proceedings*, the journal of the National Academy of Sciences, included an article suggesting that a chemical in marijuana may ease strokes. So far the chemical has only been tested on rats, but scientists are hopeful that the pure chemical cannabidiol will eventually be used to help stroke victims. The scientists caution that it is unlikely that anyone could get a protective dose of cannabidiol from smoking marijuana.[32]

B. The evidence supporting "medical marijuana" is largely anecdotal and the latest in depth study indicated that more research was required.

Pro-marijuana arguments heavily rely on anecdotal evidence instead of controlled studies. Many people make the claim that marijuana use has helped control aspects of various diseases. However, anecdotes are notoriously inaccurate or statistically misleading.

Robert Peterson, the director of Michigan's Office of Drug Control Policy from 1991-1995, wrote, "One must look closely at anecdotal evidence. In some of the most celebrated cases, the individual smoked pot before he or she ever got ill. Marijuana is addictive and addicts tend to feel better when they receive their drug. . . . There is no doubt that using a euphoric drug such as marijuana, alcohol,

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[31] Letter from Philip R. Lee, Assistant Secretary for Health, Dep't of Health & Human Services, to Rep. Dan Hamburg, U.S. House of Representatives, (July 13, 1994).

[32] A.J. Hampson et al., *Cannabidiol and Delta-9 tetrahydrocannabinol are neuroprotective antioxidants*, 95 Proceedings 8268, 8271 (1998).

cocaine or heroin will make a sick person feel better. That does not make a drug a medicine."[33]

The DEA petition echoes Peterson. "Sick people are not objective scientific observers, especially when it comes to their own health. We all have heard of the placebo effect. Patients have a tendency to respond to drugs as they believe is expected of them. . . Stories of marijuana's benefits from sick people with a prior history of marijuana abuse may be based on rationalizations caused by drug dependence, not on any medical benefits caused by the drug."[34]

IOM's only explicit recommendation regarding smoked marijuana was limited to strictly controlled, short-term clinical trials with the aim of separating the benefits of cannabinoids from the joint itself - a far cry from the relatively freewheeling plans of advocates of smoked marijuana and the Oakland Cannabis Buyer's Club. Although the Executive Summary of the report suggested that a small number of individuals might be given marijuana until the completion of the development of other THC delivery options, this was not one of the official recommendations made by the report, which strongly discouraged the use of smoked marijuana, citing the side effects and hazardous delivery system.[35]

The 1999 IOM paper recommended that clinical trials of smoked marijuana be conducted, but the goal "would not be to develop marijuana as a licensed drug, but rather as a first step towards the possible development of nonsmoked, rapid-onset cannabinoid delivery systems."[36] An inhaler is an example of such a delivery system. The IOM recommended that these trials, if implemented, last no longer than six months. Other qualifications on such trials

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[33] Robert E. Peterson, *Experts Agree: There Is No Medical Use for Marijuana*, Ann Arbor News, Apr. 7, 1994, at A12.

[34] Marijuana Scheduling Petition, 57 Fed. Reg. 10,499 (1992).

[35] *Marijuana, supra* note 10, at 8-9.

[36] *Id.* at 8.

include the following: documented failure of all approved medications for patients enrolled in trials; the expectation that cannabinoid drugs will relieve the specified symptom; administration of marijuana under close medical supervision; and oversight of trials by an agency similar to an institutional review board.[37]

III. PERMITTING "MEDICALIZATION" OF CRUDE MARIJUANA WOULD RESULT IN MANY NEGATIVE CONSEQUENCES THAT THE FEDERAL DRUG LAWS ARE DESIGNED TO PREVENT.

A. Medicalization of marijuana changes society's (particularly children's) attitudes toward the perceived dangerousness of illicit drug use.

Drug use among American adolescents is already high. In a government sponsored survey, *Monitoring the Future*, the University of Michigan's Institute for Social Research and the National Institute of Drug Abuse found that past-month use of marijuana is climbing. More than a fifth (21.6 percent) of all 12th graders had used marijuana in the past month, and current use among 8th graders (9.1 percent) and 10th graders (19.7 percent) continues to rise.[38]

This increase in use is a dangerous trend. An October 1999 article in the *American Journal of Public Health* found that at-risk children include those with friends using marijuana.[39] It also found the following:

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[37] *Id.* at 9.

[38] Univ. of Mich. Inst. for Social Research and the Nat'l Inst. of Drug Abuse, *Monitoring the Future* app. (2000).

[39] M. Whiteman, *The Risks for Late Adolescence of Early Adolescent Marijuana Use*, 89 Am. J. of Pub. Health 1549, 50 (1999).

"Early adolescent marijuana use is related to later adolescent problems that limit the acquisition of skills necessary for employment and heighten the risks of contracting HIV and abusing legal and illegal substances."[40]

"Future risks to adolescents who smoke marijuana include not finishing high school; delinquency; multiple sexual partners; not practicing "safe sex"; believing that drugs are not harmful; cigarette, alcohol, and/or marijuana abuse; and friends with significant deviant behavior."[41]

Studies reveal that adolescents' marijuana use is linked to their perception of its harm. As kids perceive more harm associated with marijuana, use declines.[42] A 1997 government survey of 12-to 17-year-olds in Arizona (a state that legalized "medical marijuana" at the same time as California) found considerably higher rates of current drug use than elsewhere in the country: 16.8 percent of Arizona youth were current users compared to 11.9 percent elsewhere. Nearly 12 percent of Arizona youth were current marijuana users, compared with 9.9 percent of youth in the remainder of the Untied States. The number of current drug users of all ages was higher in California (8.3 percent) and Arizona (8.4 percent) than in the remainder of the United States (6.1 percent).[43]

A 1997 Partnership for a Drug-Free America survey found that California teens are less likely than peers in other states to think that marijuana experimentation or use is risky; more likely to believe marijuana use is legal; more likely to believe that making marijuana legal as a medicine means it "isn't as harmful as I used to think"; and likely to

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[40] *Id.* at 1549.

[41] *Id.*

[42] Substance Abuse and Mental Health Services Admin., Nat'l Inst. Of Health, *Summary of Findings from the 1998 National Household Survey on Drug Abuse* 29 (1999).

[43] Substance Abuse and Mental Health Services Admin., Nat'l Inst. Of Health, *1997 National Household Survey* 3 (1997) [hereinafter *Household*].

believe that legalizing for medical purposes makes it "easier for kids my age to try marijuana."[44]

The drug-soaked Dutch have also witnessed this phenomenon. In 1984, the Netherlands essentially decriminalized cannabis. Today, there are more than 350 so-called "coffee shops" across that country where customers can legally purchase cannabis and hashish. Meanwhile, based on Dutch government adolescent drug-use surveys, teen cannabis use has skyrocketed. Between 1984 and 1996, among 12- to 18-year-olds, lifetime and current cannabis smoking rose 400 and 500 percent respectively.[45]

U.S. Attorney Jay McCloskey, Maine's top federal law enforcement official, told the *Portland Press Herald*, "[Maine's 1999 medicinal marijuana referendum] sends a very bad message to our young people, that drugs won't hurt you, that they aren't bad, that they are medicine. ... It's one more step down that road toward legalizing marijuana."[46]

"The argument about medicinal marijuana carries a greater threat to changing juvenile attitudes than any policy that's adopted," stated Mark Kleiman, a specialist in drug policy at the University of California at Los Angeles.[47]

B. Medicalization, particularly of the type practiced in California, makes marijuana much more available for illicit use.

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[44] Partnership for a Drug-Free America, *Teens' Attitudes Toward Marijuana* 4,5 (1997).

[45] S.B.M. Kuipers and W.M. de Zwart, *Trends and Patterns in Illicit Drug Use among Students Aged 12 to 18 in the Netherlands*, 29 J. of Drug Issues 549, 554, 555 (1999).

[46] Peter Pochna, *Lines Drawn on Medicinal Marijuana Use*, Portland (Maine) Press Herald, Oct. 11, 1999, at. A1.

[47] Paul Van Slambrouck, *What Teens Hear in Marijuana Debate*, The Christian Science Monitor, Mar. 22, 1999, at 1.

California allows marijuana to be grown and smoked for any illness for which it could provide relief, without age restriction. *Illness* is loosely defined, including headaches, chronic pain, and arthritis. Only a doctor's oral recommendation is required.

Marijuana contains cannabinoids which may have some moderate effect on the symptoms of certain illnesses, but that doesn't mean it should be made available in the manner recommended by the Oakland Cannabis Buyer's Cooperative. While cocaine, like Marinol, is a Schedule II drug which doctors may prescribe,[48] the government rightly assures it is distributed under very controlled circumstances, not by a "Cocaine Buyer's Cooperative." A Schedule I drug with dangerous side effects and a hazardous delivery system should be subject to stringent controls that are noticeably absent in California.

In California, there has been an emergence of "Pot Clubs" where people go to acquire and use marijuana. These clubs either bypass laws prohibiting the sale of marijuana (asking for "donations" instead), or they simply operate in direct violation of laws. These practices lead to a breakdown in drug enforcement policy and give individuals an opportunity to obtain marijuana without necessarily having the legal right to do so.

In San Francisco, "local law enforcement officials maintain a hands-off policy toward the clubs." The refusal of police to monitor individuals using these clubs leads to abuse of the law. The radical homosexual group, "Act Up," runs a dispensary on Market Street where "only those who have signed a notarized statement under penalty of perjury that they need marijuana for a medical condition and have discussed it with their doctor are eligible. They don't verify the statements, or ask for documentation."[49]

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[48] 21 U.S.C. § 812 (2000).

[49] Ulysses Torassa, *City's Pot Clubs Live On*, The San Francisco. Examiner, June 13, 1999, at D1.

On December 12, 1997, a California appeals court found:

> [The San Francisco club] generally demonstrate[d] an indiscriminate and uncontrolled pattern of sale to thousands of persons among the general public, including persons who had not demonstrated any recommendation or approval of a physician and, in fact, some of whom were not under the care of a physician, such as undercover officers. Young children were seen wandering in and out of the premises, and some persons who had purchased marijuana on respondents' premises were reselling it unlawfully on the street. The declarations also reveal that respondents were importing marijuana, in violation of section 11360(a).[50]

San Jose, Calif., allows "medical" marijuana distribution centers within 500 feet of schools, day care centers, and churches, and within 150 feet of residential areas.[51]

Enforcement officers in Arcata, Calif., faced a "law enforcement nightmare" after Proposition 215 was passed: "The city lost thousands of dollars trying to determine whether or not the smokers' claims were legitimate."[52] In order to ease problems relating to police enforcement of this type of legislation, many states are issuing identity cards showing that an individual qualifies for medicinal marijuana. These cards are coming under attack as a violation of patient-doctor confidentiality privilege and a patient's privacy of health records (and, therefore, a violation of an individual's civil liberties).

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[50] *Lungren v. Peron*, 59 Cal. App. 4th 1383 (Cal. Ct. App., Dec. 12, 1997).

[51] Maria Alicia Gaura, *San Jose Says Pot Club Has Broken Zoning Laws*, The San Francisco Chronicle, Apr. 30, 1997, at A15.

[52] Noah Isackson, *Arcata's Police Chief Hands Out 'Pot Cards' to Medical Marijuana Smokers*, Associated Press, Apr. 10, 1999, *available in* Lexis-Nexis.

Marion County, Ore., District Attorney Dale Penn said, "There have been a few individual cases here and there where an individual has attempted to use the marijuana law as an after-the-fact excuse [after being arrested for illegally possessing marijuana]."[53]

While the 1999 IOM report authors found no evidence that drug use in general would rise if marijuana were sanctioned as medicine, they qualified their statement by relying on the supposition that medical use of marijuana would be "as closely regulated as other medications with abuse potential."[54] The method of distribution permitted in California does not come close to meeting the standard the IOM authors relied on when making their statement.

C. There is a high correlation between marijuana use and many social and public health harms.

Marijuana is a dangerous drug. Marijuana is a Schedule I controlled substance (21 U.S.C. § 812), defined as having a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for use. It affects memory, perception, judgment, and complex motor skills, such as those needed for driving and flying.

Marijuana is an addictive drug. In 1996, a total of 195,000 Americans entered treatment for marijuana, 62 percent of whom were under age 25.[55]

Studies find that a high percentage of reckless drivers and accident victims used marijuana. A study

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[53] Brad Cain, *New Medical Pot Law Working Smoothly*, Associated Press, Aug. 11, 1999, *available in* Lexis-Nexis.

[54] *Marijuana*, *supra* note 10, at 7.

[55] Joseph A. Califano, Jr., *Casa's Non-Medical Marijuana Report*, Address before The National Center on Addiction and Substance Abuse at Columbia University (July 1999), <http://www.casacolumbia.org/newsletter1457/newsletter_show.htm?doc_id=15629>.

testing urine samples of reckless drivers who were not obviously drunk from alcohol found that 59 percent of the drivers tested positive for cocaine and marijuana. Another study of more than 1,000 accident victims found that 35 percent had detectable levels of marijuana in their blood.[56]

In 1997, there were 64,744 marijuana-related emergency room episodes. This is a 200 percent increase since 1988.[57]

Delinquent student behavior is linked to marijuana use. Studies show that delinquent behavior such as cutting classes, stealing, attacking people, and destroying others' property increases with frequency of marijuana use.[58] A 1992 Center for Disease Control and Prevention survey found that marijuana-using adolescents drop out of school more often than non-users.[59] A 1995 study showed marijuana produces cognitive impairment.[60] A 1998 University of Maryland study found that marijuana use is highly correlated with delinquent and depressive behaviors. Among twelve to seventeen-year-olds who ran away from home, 24 percent reported weekly marijuana use; only 4 percent reported no use. Among the same age group, 26 percent of those who had physically attacked people reported weekly marijuana use, and 24 percent of those who

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[56] Alan Leshner, *New Marijuana Facts from NIDA*, The Wash. Post, Oct. 5, 1994, at A22.

[57] Office of National Drug Control Policy, Executive Office of the President, *Trends in Drug-Related Emergency Room Episodes and Selected Drug Mentions, 1988-97, in National Drug Control Strategy* 128 (1999).

[58] Office of National Drug Control Policy, Executive Office of the President, *America's Drug Use Profile, in National Drug Control Strategy* 19 (1999).

[59] *National, supra* note 26, at 125.

[60] Nadia Solowij et al., *Differential Impairments of Selective Attention due to Frequency and Duration of Cannabis Use*, 37 *Biological Psychiatry*, 731, 731 (1995).

thought about suicide smoked the drug weekly. In each case, the weekly users constituted pluralities.[61]

Adolescent users are three or more times likelier than non-users to commit theft, vandalism, driving under the influence, battery and selling of illegal drugs.[62] In 1998, the Arrestee Drug Abuse Monitoring program found that "among juvenile arrestees, marijuana is overwhelmingly the primary drug of use."[63] Positive rates for marijuana among male juvenile arrestees ranged from 64 percent in Phoenix to 35 percent in San Jose.[64]

Marijuana use is related to adult crime as well. In 1998, the percentage of all male adult arrestees testing positive for marijuana ranged from a low of 25.8 percent in Las Vegas to a high of 50.2 percent in St. Louis, Mo.[65] Other national surveys show a strong marijuana use and crime. In 1997, of all Americans aged 12 and older, 71 million (32.9 percent) had used marijuana at some point. Five percent used marijuana in the past month.[66] In comparison, in 1996,

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[61] *Practitioners Should Be Aware of Co-Occurring Marijuana Use and Delinquent/Depressive Behaviors Among Youth* CESAR Fax (Univ. of Md., College Park, Md.), Nov. 9, 1998 [hereinafter *Practitioners*].

[62] *Teen Marijuana Users Report Psychosocial Problems*, SAMHSA News (Substance Abuse and Mental Health Services. Admin., U.S. Dep't of Health and Human Services, Wash., D.C.), Summer 1998, at 2.

[63] Arrestee Drug Abuse Monitoring Program (ASAM), U.S. Dep't of Justice, *1998 Annual Report on Drug Use Among Adult and Juvenile Arrestees* 3 (1998).

[64] *Id.*

[65] In 1996, there were 28,587 (8 percent of total) drug-related felony convictions based on trials in state courts. Of that number, 12,228 were for possession. In 1996, 319,185 (92 percent of total) drug-related felony convictions were based on guilty pleas. Of that number 123,040 were for possession. Bureau of Justice Statistics, U.S. Dept. of Justice, *Felony Convictions in State Courts, in Source Book of Criminal Justice Statistics* 432 (1998).

[66] *Household, supra* note 43, at 16.

of all jail inmates, 78.2 percent had used marijuana at some point. More than half (54.9 percent) had been regular marijuana users. One-third (36.8 percent) used marijuana in the month before the offense and 18.5 percent used marijuana at the time of the offense.[67]

A 1999 survey of professionals who work in child welfare agencies or family courts found that three of four professionals cite substance abuse as one of the top three causes for the rise in child maltreatment. Marijuana is linked to 20.5 percent of these cases.[68]

According to a 1990 article in the *Journal of the American Medical Association*, marijuana users caused 55 percent more industrial accidents than non-users, and had 85 percent more injuries at work than non-users.[69]

In addition to the costs of medical care for workplace accidents, pregnancy problems, and the treatment of victims of marijuana-using criminals, marijuana contributes to national health costs through marijuana-related visits to hospital emergency rooms. Marijuana-related emergency room visits rose during the 1990s from an estimated 16,251 in 1991 to 76,870 in 1998.[70]

D. Past periods of partial legalization of marijuana have produced negative consequences.

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[67] Bureau of Justice Statistics, U.S. Dept. of Justice, *Sourcebook of Criminal Justice Statistics* 508 (1998).

[68] The Nat'l Ctr on Addiction and Substance Abuse at Columbia Univ., *No Safe Haven: Children of Substance-Abusing Parents* 14 (1999).

[69] Zwerling et al., *The Efficacy of Pre-Employment Drug Screening for Marijuana and Cocaine in Predicting Employment Outcome*, 264 JAMA 2639, 2643 (1990).

[70] *Practitioners, supra* note 61.

California lessened the penalty for possession of one ounce or less of marijuana in 1976, and, within the first six months, arrests for driving under the influence of drugs rose 46 percent for adults and 71.4 percent for juveniles.[71] In 1975, the Alaskan Supreme Court invalidated certain sections of the state's criminal code pertaining to the possession of marijuana. Based on this finding, from 1975 to 1991, possession of up to four ounces of the drug by an adult who was lawfully in the state of Alaska became legal. The court's holding did not effect the statutory provisions dealing with the purchase, sale or manufacture of marijuana, which remained illegal during this period. Even though marijuana remained illegal for children, marijuana use rates among Alaskan youth increased significantly. In response, concerned Alaskans, in particular the National Federation of Parents for Drug-Free Youth, sponsored an anti-drug referendum that was approved by the voters in 1990, once again rendering marijuana illegal.[72]

After Massachusetts passed a law permitting "medical" marijuana use, the Supreme Judicial Court ruled that the general interest in protecting the safety of employees and providing them a drug-free environment in which to work was insufficient to justify a drug-testing program.[73]

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[71] Peggy Mann, Committee of Correspondence, *Reasons to Oppose Legalizing Illegal Drugs* (1988).

[72] *The Drug Legalization Movement in America: Hearing Before the Subcomm. On Criminal Justice, Drug Policy, and Human Resources of the House Comm. On Government Reform and Oversight*, 106th Cong. (1999) [hereinafter *Hearings*] (testimony of Barry R. McCaffrey, Director, Office of National Drug Control Policy, available at http://www.house.gov/reform/cj/hearings/99.6.16/mccaffrey.htm.

[73] Jana Howard Carey, *Courts Weigh Drug Testing's Impact on Worker Privacy under State Law*, Employment Testing, Jan. 1997, at 1.

The Netherlands, one of the countries most celebrated for its loose drug laws, has also experienced negative effects from legalization for possession and small sales of marijuana. The softening of Dutch criminal laws against marijuana has led to a normalization of drug use more broadly.[74] When the so-called Dutch "coffee shops" started selling marijuana in small quantities, use of the drug more than doubled between 1984 and 1996 among eighteen to twenty five year-olds.[75] Dutch tolerance of drug use has created a climate that drug manufacturers and traffickers have seized upon to produce and market more addictive and dangerous drugs. This has led to the Netherlands becoming a major producer of illicit synthetic drugs.[76]

E. Marijuana is a "gateway" drug for many users.

The "gateway" theory is derived from the observation that most users of cocaine and heroin began their illicit drug "careers" with marijuana, tobacco cigarettes, and alcohol. Conversely, children who never use marijuana are much less likely to use harder drugs in the future than those who do smoke marijuana.

The 1999 IOM report noted that the theory that marijuana "serves as a gateway to the world of illegal drugs in which youths have greater opportunity and are under greater social pressure to try other illegal drugs . . . is supported by - although not proven by - the available data."[77]

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[74] Larry Collins, *Holland's Half-Baked Drug Experiment*, Foreign Affairs, May-June 1999, at 83-7, 88-9, 91-8.

[75] S.B.M. Kuipers and W.M. de Zwart, *Trends and Patterns in Illicit Drug Use among Students Aged 12 to 18 in the Netherlands*, 29 J. of Drug Issues 549, 554, 555 (1999).

[76] *Hearings, supra* note 72. (testimony of Barry McCaffrey).

[77] *Marijuana, supra* note 10, at 3.22.

The National Center on Addiction and Substance Abuse (CASA) is perhaps the best-known advocate of the gateway theory. In 1994, CASA published "Cigarettes, Alcohol, Marijuana: Gateways to Illicit Drug Use." That report demonstrated that adolescents who used alcohol, cigarettes and marijuana were far more likely to use drugs like cocaine than those who did not. In a subsequent publication ("Substance Abuse and the American Adolescent"), CASA researchers compared risk factors for adolescents, such as fighting and driving drunk, with the use of illicit drugs. They found that among 12- to 17-year-olds who reported no other problem behaviors, current users of cigarettes, alcohol and marijuana were almost 17 times likelier also to have used a harder drug like cocaine.[78] While CASA acknowledged that these findings were statistical rather than causal correlations, it noted:

> These relationships between use of gateway substances and other illegal drug use are more potent than early statistical relationships found between smoking and lung cancer (nine to ten times likelier in the 1964 Surgeon General's report) and between high cholesterol and heart disease (two to four times likelier in the early phases of the Framingham Heart Study).[79]

F. Medicalization is a pretense used by many advocates of legalization.

An April 1999 article in *Proceedings of the Association of American Physicians* states, "Most supporters of smoked marijuana are hostile to the use of purified chemicals from marijuana, insisting that only smoked marijuana leaves be used as 'medicine,' revealing clearly that their motivation is

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[79] The Nat'l Ctr on Addiction and Substance Abuse at Columbia Univ., *Substance Abuse and the American Adolescent* 22 (1997).

not scientific medicine but the back door legalization of marijuana."[80]

Keith Stroup, founder and executive director of NORML, announced almost 20 years ago that NORML would use the issue of "medical" marijuana to legitimize pot. He was quoted in the February 6, 1979, edition of the *Emory Wheel* (Emory University), as follows: "We are trying to get marijuana reclassified medically. If we do that ... [we will] be using the issue as a red herring to give marijuana a good name."[81]

Ethan Nadelmann, who directs the pro-drug Lindesmith Center for billionaire financier George Soros, said, "These election results send a clear message. ... It was a message for pragmatism and common sense in dealing with drugs. ... Ultimately our drug policy should be based upon one very simple notion: that people should not be discriminated against based upon the substances they consume."[82]

Officials who deal with the problem every day understand the radical agenda behind the subculture's push for "medical" marijuana.

Washington state's lieutenant governor Brad Owen worked against Initiative 692, which legalized "medical marijuana" in that state in 1998. He argued that the initiative proponents' agenda goes far beyond prescribing marijuana for sick people, saying, "The first step to legalizing drugs is to accept medical marijuana."[83]

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[80] Robert DuPont, *Examining the Debate on the Use of Medical Marijuana*, 111 Proceedings of the Ass'n of Am. Physicians 166, 166 (1999).

[81] *NORML Chairman Keith Stroup Talks on Pot Issues*, Emory Wheel, Feb. 6, 1979, at 19.

[82] Ethan Nadelmann, Keynote Address at Nat'l Organization for the Reform of Marijuana Laws Annual Conference (Nov. 12, 1998).

[83] David Schaefer, *Marijuana Initiatives Bloom Around West* The Seattle Times, Aug. 20, 1998, at B1.

In 1999, Barry McCaffrey, director of the Office of National Drug Control Policy, warned a congressional committee of "a carefully camouflaged, well-funded, tightly knit core of people whose goal is to legalize drug use in the United States."[84]

In June 1999, Drug Enforcement Administration (DEA) Deputy Administrator Donnie Marshall told a U.S. House of Representatives committee, "I suspect that medical marijuana is merely the first tactical maneuver in an overall strategy that some hope will lead to the eventual legalization of all drugs."[85]

In 1996, former presidents Bush, Carter and Ford cautioned, "Both initiatives [California's and Arizona's] are hoaxes that seek to cloak drug legalization under the guise of compassion for the ill or strengthening drug laws."[86]

CONCLUSION

For all of the above reasons, your *amicus curiae* pray that this Honorable Court will reverse the judgment of the Court of Appeals for the Ninth Circuit and reinstate the preliminary injunction entered by the U.S. District Court for Northern California against certain cannabis clubs and their agents, including Respondents, Oakland Cannabis Buyers' Cooperative and Jeffrey Jones, *et al.*

January 10, 2001

Respectfully submitted,

Janet M. LaRue

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[84] Christopher S. Wren, *Small Coalition Crusades against America's War on Drugs*, The San Diego Union-Tribune, Jan. 2, 2000, at A14.

[85] Michael Doyle, *Two Groups Roll out DEA Applications to Grow Marijuana*, The Fresno Bee, June 21, 1999, at A1.

[86] Office of Nat'l Drug Control Policy, Executive Office of the President, *Dear Fellow Citizens: An open letter from President George Bush, President Jimmy Carter, and President Gerald Ford, Oct. 29, 1996*, Medical Marijuana Information Packet.

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In The

Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF AMICUS CURIAE STATE OF CALIFORNIA, IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE

In November 1996, the voters of the State of California adopted Proposition 215, the Compassionate Use Act of 1996, approving the use of cannabis for seriously ill people. The State of California seeks to protect the sovereign interest of its jurisdiction and specifically those of its electorate. The State of California has a unique and constitutionally protected interest in the enactment of a state initiative addressing the health and welfare of its citizens. The initiative enacted by the voters of the State of California is an expression of their will reflecting what they believe ought to be lawful conduct in California. To the extent the citizens of the various states, independently and collectively, do not disturb the national interest, the Ninth and the Tenth Amendments to the United States Constitution guarantee the states the privilege of debating the issue of whether their citizens may utilize cannabis to treat serious illness. The electorate in California have declared their view on this question and it should be respected by this Court as a democratic exercise properly reserved to the states.

The states are the laboratories of democracy in our federal system. (*Washington v. Glucksberg*, 521 U.S. 702 (1997); *Cruzan v. Missouri Dept. of Health*, 497 U.S. 261, 292 (1990); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932), Brandeis, J., dissenting.) The Constitution does not prevent the states from expressing their preference for allowing citizens to use cannabis to treat serious illness.

The opinion of the Court of Appeals directing the district court to craft an injunction broad enough to prohibit illegal conduct, but narrow enough to exclude conduct that is likely privileged or justified due to medical necessity, is congruent with Proposition 215. The voters of California sought to make cannabis available to seriously ill people. The district court's modification of its injunction permitting seriously ill Californians to use cannabis for medicinal purposes is a proper exercise of the board equitable discretion vested in that court.

The modified injunction limits the use of cannabis to a very narrow class of people. The injunction sets forth clear and enforceable conditions for the use of cannabis by seriously ill persons who have no other legal alternatives. This injunction is consistent with the spirit and intent of the Compassionate Use Act of 1996.

The authority of the states to debate and decide matters of medical necessity is not an appropriate subject of federal review. The states have a sovereign interest in matters pertaining to the health and welfare of their citizens, and the state ballot initiative process is a valid and lawful manner for those citizens to develop policy in these areas. California's voters have spoken. The State of California submits that this Court should protect the ability of her citizens to do so.

ARGUMENT

A. INTRODUCTION

Since 1996, eight states and the District of Columbia, have had ballot initiatives authorizing the use of cannabis

for seriously ill people approved by their respective voters. In California, voters passed Proposition 215, the Compassionate Use Act of 1996. The Compassionate Use Act provides in relevant part as follows:

> "The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:
>
> > (A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.
> >
> > (B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction. . . . "

(Cal. Health & Saf. Code § 11362.5(b)(1)). The Act also provided that cannabis used for non-medicinal purposes remained prohibited: "Nothing in this section shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others, nor to condone the diversion of marijuana for nonmedical purposes." (Cal. Health & Saf. Code § 11362.5(b)(2).)

In 1970, Congress passed the Controlled Substances Act, classifying cannabis as a "Schedule I" drug which means: "The drug or other substance has a high potential

for abuse; the drug or other substance has no currently accepted medical use in treatment in the United States; there is a lack of accepted safety for use of the drug or other substance under medical supervision." (21 U.S.C. § 812.)

In January 1998, the federal government filed a civil action in the United States District Court for the Northern District of California, seeking an injunction prohibiting respondent from distributing cannabis to seriously ill people in Oakland, California. On May 19, 1998, the district court issued a preliminary injunction enjoining respondent from providing cannabis to seriously ill people.

Following a subsequent appeal to the Ninth Circuit Court of Appeal, the district later modified its injunction to permit distribution of cannabis to patients who suffer from a serious medical condition, who desire and need cannabis, and who have no other "legal alternatives for the effective treatment or alleviation of the patient-members' condition . . . . " (District Court Decision of July 17, 2000 at p. 2.)

The State of California contends the district court's modification of its injunction is congruent with the ballot initiative approved in its states. The Compassionate Use Act of 1996 represents a sovereign expression of choice by California voters that cannabis should be available to seriously ill persons. The district court's injunction represents a clear, enforceable, and narrow judicial order allowing seriously ill people with no other legal alternatives the option to alleviate or treat their symptoms or illness by using cannabis when recommended by a licensed physician.

Amicus submits the district court's injunction is sufficiently narrow that only those whose conduct would likely be privileged, excused or justified may use cannabis. This exercise of the lower court's broad equitable discretion does not disrupt the federal government's ability to enforce the Controlled Substances Act. The injunction is broad enough to prohibit illegal conduct.

The Controlled Substances Act unduly interferes with the privilege afforded the states by the Ninth Amendment to enact voter approved initiatives protecting the health, safety and welfare of their citizens.

Finally, the State of California contends application of the Controlled Substances Act to prohibit the use of cannabis by seriously ill persons in states which have voter approved ballot initiatives violates traditional notions of state sovereignty protected by the Tenth Amendment.

This Court should protect the interest of California's citizens and affirm the district court's modification of the preliminary injunction allowing seriously ill persons with no other legal alternatives to use cannabis to treat their symptoms or illness.

B. THE CONTROLLED SUBSTANCES ACT UNDULY INTERFERES WITH THE NINTH AMENDMENT ABILITY OF STATES TO ENACT VOTER APPROVED LEGISLATION

The State of California contends application of the Controlled Substances Act by the federal government to prohibit seriously ill citizens of California from using cannabis pursuant to the Compassionate Use Act unduly

interferes with its sovereign privilege to address matters of health, safety and welfare through the ballot initiative process. The issue of whether cannabis should be used by seriously ill patients is a controversial subject area, best decided by the states through the democratic process. This is precisely what happened in 1996, when voters in California approved Proposition 215 through a ballot initiative. This Court should not overturn what the democratic process has sanctioned in California.

i. The Ninth Amendment Limits the Power of Congress and the Federal Government to Enact Legislation Interfering with State Sovereignty.

The Ninth Amendment limits the power of Congress and the federal government to pass legislation that unduly interferes with California's interest in regulating the health, safety and welfare of its citizens. As applied, the Controlled Substances Act appears to prohibit seriously ill Californians from using cannabis. The State of California maintains this type of intrusion by the federal government is prohibited by the Ninth Amendment.

The Ninth Amendment states: "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people." The Court has on limited occasions addressed the scope of the Ninth Amendment.

In *Griswold v. Connecticut*, 381 U.S. 479 (1965), both Justice Goldberg in his concurring opinion, and Justice Black in his dissenting opinion, discussed the scope of the Ninth Amendment as applied to the federal government.

Justice Goldberg, concurring, wrote: "The language and history of the Ninth Amendment reveal that the Framers of the Constitution believed that there are additional fundamental rights, protected from government infringement, which exist alongside those fundamental rights specifically mentioned in the first eight amendments." *Id.* at 488. Justice Goldberg relied on history to find that the Ninth Amendment serves two purposes: To make certain that the enumeration of specific rights would not mean other rights could be denied and to limit the federal government. He stated:

> "The Amendment is almost entirely the work of James Madison. It was introduced in Congress by him and passed the House and Senate with little or no debate and virtually no change in language. It was proffered to quiet expressed fears that a bill of specifically enumerated rights could not be sufficiently broad to cover all essential rights and that the specific mention of certain rights would be interpreted as a denial that others were protected." *Id.* at 488-489.

Justice Goldberg also commented: "The Ninth Amendment – and indeed the entire Bill of Rights – originally concerned restrictions upon *federal* power . . . " *Id.* at 493 (Emphasis in original.)

Justice Goldberg concluded by noting:

> "In sum, the Ninth Amendment simply lends strong support to the view that the "liberty" protected by the Fifth and Fourteenth Amendments from infringement by the Federal Government or the States is not restricted to rights specifically mentioned in the first eight amendments." (*Id.* at p. 493.)

Justice Black also noted that the Ninth Amendment was intended to limit the powers of the federal government: "That Amendment was passed, not to broaden the powers of this Court or any other department of 'the General Government,' but as every student of history knows, to assure the people that the Constitution in all its provisions was intended to limit the federal government to the powers expressly or by necessary implication." *Id.* at 520.

Consistent with *Griswold*, the Court in *City of Boerne v. P.F. Flores*, 521 U.S. 507 (1997), held that congressional enactment of the Religious Freedom Restoration Act of 1993 (RFRA) unduly burdened the states' traditional right to regulate the health and welfare of their citizens.

Although not expressly a Ninth Amendment case, Justice Kennedy, writing for the Court in *City of Boerne* stated: "Under our Constitution, the Federal Government is one of enumerated powers. [Citation]. The judicial authority to determine the constitutionality of laws, in cases and controversies, is based on the premise that the 'powers of the legislature are defined and limited; and that those limits may not be mistaken or forgotten, the constitution is written.' [Citation]." *Id.* at 516. In determining that the RFRA unduly interfered with the rights of the states, Justice Kennedy stated:

> "The stringent test RFRA demands of state laws reflects a lack of proportionality or congruence between the means adopted and the legitimate end to be achieved. If an objector can show a substantial burden on his free exercise, the State must demonstrate a compelling governmental interest and show that the law is the least

> restrictive means of furthering its interest . . . . This is a considerable congressional intrusion into the States' traditional prerogatives and general authority to regulate for the health and welfare of their citizens." *Id.* at 533-534.

In this case, pursuant to the traditional right "to regulate for the health and welfare of their citizens," California enacted voter approved legislation. This legislation permits the use of cannabis for medical purposes, provided that strict guidelines are adhered to. Unlike the Religious Freedom Restoration Act of 1993 in *City of Boerne*, the Controlled Substances Act does not even allow the states to "demonstrate a compelling governmental interest and show that the law is the least restrictive means of furthering its interest." *Id.* Rather, the Controlled Substances Act classifies "marihuana" as a Schedule I substance and places a blanket prohibition on the substance: "It shall be unlawful for any person knowingly or intentionally – (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense," any amount of cannabis. (21 U.S.C. § 841(a)).

Unquestionably, the Controlled Substances Act unduly intrudes into California's traditional right to regulate for the health and welfare of their citizens. The Act deprives the various states of any meaningful opportunity to act within the bounds of traditional state sovereignty. This case presents the exact scenario that James Madison expressed concern for when the Ninth Amendment was introduced. Voters from California, through the state ballot initiative process, approved a statute the federal government now seeks to prohibit. Nowhere does the

Constitution expressly give the power to regulate the usage of cannabis for medical purposes to Congress. This intrusion by the federal government into state sovereignty threatens to upset the balance of federalism and should not be permitted by this Court.

ii. The Debate Surrounding the Right of Seriously Ill Patients to Use Cannabis Is an Issue Best Suited for Resolution Through the Democratic Process in the States.

Several members of this Court have previously recognized controversial areas of social policy upon which reasonable persons may differ are best resolved through the democratic process. The State of California maintains the debate over whether to allow seriously ill patients the right to use cannabis with the advice and consent of a physician is one such controversy.

In *City of Boerne*, a case dealing with the ability of the federal government to restrict the ability of states to burden religious interests, Justice Scalia wrote: "The issue presented by *Smith* is, quite simply, whether the people, through their elected representatives, or rather this Court shall control the outcome of those concrete cases. For example, shall it be the determination of this Court, or rather of the people, whether church construction will be exempt from zoning laws? . . . It shall be the people." *Id.* at 544.[1]

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[1] The Court in *Employment Div., Dept. of Human Resources of Oregon v. Smith*, 494 U.S. 872 (1990) was presented with the issue

In *Doe v. Bolton*, 410 U.S. 179 (1973), a companion case to the controversial *Roe v. Wade*, 410 U.S. 113 (1973), decision, Justice White dissenting stated: "In a sensitive area such as this, involving as it does issues over which reasonable men may easily and heatedly differ, I cannot accept the Court's exercise of its clear power choice by interposing a constitutional barrier to state efforts to protect human life and by investing mothers and doctors with the constitutionally protected right to examine it. This issue, for the most part, should be left with the people and to the political processes the people have devised to govern their affairs." *Id.* at 222.

Chief Justice Rehnquist writing for the Court in *Washington v. Glucksberg*, 521 U.S. 702 (1997), on the issue of physician-assisted suicide stated: "By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action. We must therefore 'exercise the utmost care whenever we are asked to break new ground in this field,' [Citation], lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court. [Citation]." *Id.* at 720.

Justice O'Connor's concurring opinion in *Glucksberg* described the role of the States in formulating safeguards to protect the people as follows:

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of whether states may constitutionally refuse unemployment compensation to persons who ingest peyote as a religious practice.

> "Every one of us at some point may be affected by our own or a family member's terminal illness. There is no reason to think the democratic process will not strike the proper balance between the interests of the terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure . . . In such circumstances, 'the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance.' [Citation]." *Id.* at 737.

In *Planned Parenthood Of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), Justices O'Connor, Kennedy, and Souter wrote on the ability of the State to regulate abortion: " 'The Constitution does not forbid a State or city, pursuant to democratic processes, from expressing a preference for normal childbirth.' [Citation]." *Id.* at 872.

Justice Scalia, concurring in the judgment in part and dissenting in part, reiterated the desire to allow citizens, using the democratic process, to decide the issue of regulating abortion: "The States may, if they wish, permit abortion on demand, but the Constitution does not require them to do so. The permissibility of abortion, and the limitations upon it, are to be resolved like most important questions in our democracy: by citizens trying to persuade one another and then voting." *Id.* at 979.

Justice Scalia went on to explain the impact of denying citizens the right to use the democratic process: "By foreclosing all democratic outlet for the deep passions

this issue arouses, by banishing the issue from the political forum that gives all participants, even the losers, the satisfaction of a fair hearing and an honest fight, by continuing the imposition of a rigid national rule instead of allowing for regional differences, the Court merely prolongs and intensifies the anguish." *Id.* at 1002. Finally, Justice Scalia concluded: "We should get out of this area, where we have no right to be, and where we do neither ourselves nor the country any good by remaining." *Id.* at 1002.

The issue in this case is similar to those dealing with the right to abortion and the right to end one's life. In both areas, the Court has faced great public debate, with various groups supporting each side of the issue. In this case, the debate surrounds the use of cannabis for medical treatment.

On one side of the debate are groups and individuals such as the Family Research Council, who have submitted a separate Amicus Curiae brief in this case. They argue that cannabis is "bad medicine," the harm caused by the substance outweighs any benefits, and it leads to many social and public harms. (See Amicus Brief Of Family Research Council As Amicus Curiae In Support Of Petitioner.)

On the other side are physicians and seriously ill patients who feel that cannabis has been highly effective in the treatment of seriously ill patients, including those with AIDS and Cancer. (See Joint Appendix; Decl. Marcus A. Conant, M.D. at pp. 101-102; Declaration Lester Grinspoon, M.D. at pp. 127-130, 136).

The division between those who do and do not support the use of cannabis in medical situations, presents a unique question for both the State of California and the Court. In the aforementioned cases, the issue essentially boiled down to whether the states could impose regulations on abortion and physician-assisted suicide. Here, California has elected not to restrict or prohibit the use of cannabis by seriously ill people.

The People of California have already resorted to the democratic process by approving various state initiatives approving the use of cannabis for medicinal purposes. The federal government seeks to invalidate one of these state initiatives by challenging the district court's modification of an injunction permitting the distribution of cannabis by respondent. The lower court's injunction permits activity consistent with the will of the voters in California. California voters approved an initiative allowing her citizens to utilize cannabis for medicinal purposes. This Court should not disturb the sovereign vote of the people in the State of California. Proposition 215 represents the final expression of public debate in California on this issue. This Court must respect this initiative as a constitutional expression of regional interest.

iii. States Are Entitled to Create an Exception for Cannabis under the Controlled Substances Act Because of the Traditional State Interest in Regulating for the Health, Safety and Welfare of Citizens.

California contends that under traditional principles of state sovereignty and federalism, states are entitled to

create exceptions to the Controlled Substances Act when acting pursuant to their right to regulate for the health, safety and welfare of citizens. In this case, voters from California have approved ballot initiatives permitting the use of cannabis for seriously ill persons. These initiatives serve as an exception to the Controlled Substances Act. Exceptions to the Controlled Substances Act were discussed by this Court in *Employment Div., Dept. of Human Resources of Ore. v. Smith,* 494 U.S. 872 (1990).

In *Smith,* the issue was whether Oregon was required under the First Amendment to establish an exception to current drug laws for sacramental peyote, a Schedule I drug under the Controlled Substances Act.

Justice Scalia, writing for a majority of the Court stated:

> "Values that are protected against government interference through enshrinement in the Bill of Rights are not thereby banished from the political process. Just as a society that believes in the negative protection accorded to the press by the First Amendment is likely to enact laws that affirmatively foster the dissemination of the printed word, so also a society that believes in the negative protection accorded to religious belief can be expected to be solicitous of that value in its legislation as well. **It is therefore not surprising that a number of States have made an exception to their drug laws for sacramental peyote use.** [emphasis added]." *Id.* at 890.

Justice O'Connor concurring also stated that the states have a right to create an exception for peyote even though it is classified as a Schedule I substance under the

Controlled Substances Act: "But other governments may surely choose to grant an exemption without Oregon, with its specific asserted interest in uniform application of its drug laws, being required to do so by the First Amendment." *Id.* at 906.

Justice Blackmun dissenting suggested that states may very well be able to create an exception for peyote, in the process mentioning the medical use of marijuana:

> "The fact that peyote is classified as a Schedule I controlled substance does not, by itself, show that any and all uses of peyote, in any circumstance, are inherently harmful and dangerous. The Federal Government, which created the classifications of unlawful drugs from which Oregon's drug laws are derived, apparently does not find peyote so dangerous as to preclude an exemption for religious use. **Moreover, other Schedule I drugs have lawful uses. See Olsen v. Drug enforcement Admin., 279 U.S. App. D.C. 1, 6, n.4, 878 F.2d 1458, 1463 n.4 (medical and research uses of marijuana).** [emphasis added]" *Id.* at 912-913.

These opinions throughout the Court's decision in *Smith,* suggest a willingness to permit states to enact legislation providing for limited use of Schedule I substances. Furthermore, they suggest the Controlled Substances Act does not act as a blanket prohibition on the use of Schedule I substances.

Unlike *Smith* where the Court was asked to find an exception in both state and federal laws prohibiting the use of peyote, amicus here asks the Court to uphold voter enacted exceptions to the Controlled Substance Act. Justice Scalia's opinion in *Smith* supports resorting to the

democratic process for deciding the limitations to the Controlled Substances Act:

> "It may fairly be said that leaving accommodation to the political process will place at a relative disadvantage those religious practices that are not widely engaged in; but that unavoidable consequence of democratic government must be preferred to a system in which each conscience is a law unto itself or in which judges weigh the social importance of all laws against the centrality of all religious beliefs." *Id.* at 890.

The ballot initiative passed by the voters of California represent the type of social and economic experimenting the Court should embrace as fitting perfectly within the federal scheme reserving certain privileges to the states. Justice Brandeis, dissenting in *New State Ice Co. v. Liebmann*, 262 U.S. (1932), expressed similar approval for the actions of a single state:

> "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country. This Court has the power to prevent an experiment. We may strike down the statute which embodies it on the ground that, in our opinion, the measure is arbitrary, capricious or unreasonable. We have power to do this, because the due process clause has been held by the Court applicable to matters of substantive law as well as to matters of procedure. But in the exercise of this high power, we must be ever on our guard, lest we erect our prejudices into legal principles. If we would guide by the light of reason, we must let our minds be bold."

The Court should uphold the decision of California voters to create an exception to the Controlled Substances Act for seriously ill people with no other legal alternative to alleviate their symptoms or illness.

C. APPLYING THE CONTROLLED SUBSTANCES ACT TO PROHIBIT THE USE OF CANNABIS BY SERIOUSLY ILL PEOPLE IN CALIFORNIA VIOLATES TRADITIONAL NOTIONS OF STATE SOVEREIGNTY PROTECTED BY THE TENTH AMENDMENT.

Application of the Controlled Substances Act by the United States to prohibit the use of cannabis, by persons with serious medical conditions under narrow circumstances, violates the states' traditional right to promulgate regulations for the public health, safety and welfare of their citizens.

The Tenth Amendment states: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." In *Kansas v. Colorado*, 206 U.S. 46 (1907), the Court defined the purpose of the Tenth Amendment: "This amendment, which was seemingly adopted with the prescience of just such contention as the present, disclosed the widespread fear that the National Government might, under the pressure of a supposed general welfare, attempt to exercise powers which had not been granted." *Id.* at 90. In determining the scope of the Amendment, the Court stated: "If the Constitution in its grant of power is to be so construed that Congress shall be able to carry into full effect the powers granted,

it is equally imperative that where prohibition or limitation should be enforced in its spirit and to its entirety." *Id.* at 91.

The underlying reasoning and inherent scope of the Tenth Amendment suggests that federal enforcement of the Controlled Substances Act on the individual states violates the expressed protection given to the states. Indeed, the Court has held that individual states have a vital interest in preserving the public health, safety and welfare through state promulgated regulations. This right cannot be abridged by Congress simply because the subject matter concerns cannabis.

As early as 1859, the Court has held that states did not give up the right to act as a "sovereign over their persons and property, so far as it was necessary to preserve the peace." *Cutler v. Dibble*, 62 U.S. 366, 370 (1859). More recently, the Court has stated on several occasions that states possess a legitimate interest in regulating the health of their citizens.

In *Planned Parenthood v. Casey*, 505 U.S. 833 (1992), Justices O'Connor, Kennedy, and Souter defined the state's interest in a woman's life with respect to abortion: "The state has legitimate interests in the health of the woman and in protecting the potential life within her . . . . " *Id.* at 872. Furthermore, the Justices stated: "It follows that states are free to enact laws to provide a reasonable framework for a woman to make a decision that has such profound and lasting meaning." *Id.*

Justice Stevens concurring in *Washington v. Glucksberg*, 532 U.S. 702 (1997) wrote:

> "The State has an interest in preserving and fostering the benefits that every human being may provide to the community – a community that thrives on the exchange of ideas, expressions of affection, shared memories and humorous incidents as well as on the material contributions that its members create and support." *Id.* at 741.

Chief Justice Rehnquist writing for the Court on the issue of the right to die, in the case of *Cruzan v. Missouri*, 497 U.S. 261 (1990) stated:

> "But in the context presented here, a State has more particular interests at stake. The choice between life and death is a deeply personal decision of obvious and overwhelming finality. We believe Missouri may seek to safeguard the personal element of this choice through the imposition of heightened evidentiary requirements." *Id.* at 281.

Again, history helps to shed some light on the issue before the Court in this case. Nearly a century ago, the Court recognized the power of the states to enact laws for the safety and health of its citizens. In *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the Court compared the right of a state to enact laws for the health and safety of its citizens to the principle of self-defense: "Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." (*Id.* at 27.) In *Jacobson*, the Court dealt with an issue similar to the one in this case. There, the debate concerned a Massachusetts law that required smallpox vaccinations to prevent the spread of the disease. At the time of *Jacobson*,

there was a great debate concerning the effectiveness of a smallpox vaccination throughout the world. (*Id.* at 35.) Nevertheless, the Court stated:

> " 'The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action; for what the people believe is for the common welfare must be accepted as tending to promote the common welfare, whether it does in fact or not. Any other basis would conflict with the spirit of the constitution, and would sanction measures opposed to a republican form of government. While we do not decide and cannot decide that vaccination is a preventive of smallpox, we take judicial notice of the fact that this is the common belief of the people of the State, and with this fact as a foundation we hold that the statute in question is a health law, enacted in a reasonable and proper exercise of the police power.' [Citation]." *Id.* at 35.

In this case, as in *Jacobson*, the voters of California have expressed their belief that cannabis should be available to persons with a serious illness who have no other legal alternative to treat their symptoms or illness. The federal government threatens to cross the line of state sovereignty and interfere with a traditional state right.

Today, there is no doubt that medical knowledge would not question the benefit of a small pox vaccination. In the early 1900's, however, there was a heated debate, over which reasonable minds did disagree. Cannabis is no different. The Court did then as it should now, refrain from upsetting the balance of federalism under the Tenth Amendment and imposing beliefs of the Court on the public. The actions of the federal government infringing on an established right of the states to enact voter approved legislation to protect the welfare and safety of those voters, violates the Tenth Amendment.

CONCLUSION

The State of California respectfully requests the decision of the district court modifying its injunction to permit the use of cannabis by seriously ill Californians be affirmed. The lower court's injunction is sufficiently broad enough to prohibit illegal conduct proscribed by the Controlled Substances Act, but narrow enough to accommodate seriously ill people who may need cannabis to alleviate suffering. The district court's order is congruent with Proposition 215.

Proposition 215 does not disturb the balance of federalism or enforcement of the Controlled Substances Act. Indeed, the initiative is a sovereign expression of social policy voiced through the democratic process. The district court's order, as modified, is consistent with Proposition 215 and should be respected by the federal government and this Court so seriously ill people who

have exhausted conventional methods of therapy can use cannabis to relieve their suffering.

February 19, 2001

Respectfully submitted,

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IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA,
Petitioner,
v.
OAKLAND CANNABIS BUYERS' COOPERATIVE,
and
JEFFREY JONES,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF *AMICUS CURIAE* OF SHERIFF MARK N. DION (CUMBERLAND COUNTY, MAINE), (MAINE) SENATOR ANNE RAND, (CALIFORNIA) SENATOR JOHN VASCONCELLOS, NEW MEXICO GOVERNOR GARY JOHNSON, AND DKT LIBERTY PROJECT IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST[*]

Amici Curiae Mark N. Dion, Anne Rand, John Vasconcellos, and Gary Johnson are among the thousands of State and local government officials who have worked to enact and enforce State measures aimed at meeting the medical needs of those seriously ill persons for whom marijuana has proven to offer otherwise unavailable relief. *Amicus* DKT Liberty Project is a not-for-profit organization founded in 1997 with the aim of promoting and protecting civil liberties. It has actively supported these innovative State and local government efforts to safeguard the rights and interests of the seriously ill.

Although no question of the legality of these State measures is before the Court in this case – and we believe that the questions of Federal law that *are* squarely presented may be resolved exclusively through ordinary statutory interpretation tools – we are concerned that this case not be resolved based on misperceptions about the purpose or effect of these laws and that it not be decided in a manner that "pretermit[s] . . . responsible solutions being considered" at the State level. *Murray v. Giarratano*, 492 U.S. 1, 14 (1989) (Kennedy, J., concurring in judgment).

SUMMARY OF ARGUMENT

This case arises at a time of significant change in the scientific, legislative, and public opinion climate concerning the use of marijuana for therapeutic purposes by persons suffering from acute pain and debilitating illness. Rigorous scientific evidence documenting the specific benefits of marijuana for particular medical conditions is accumulating, *see* National Academy of Sciences/Institute of Medicine, *Marijuana & Medicine: Assessing the Science Base* (1999) ("IOM Report"), and this body of evidence – along with increased discussion and

---

[*] Consent to file this Brief has been sought and obtained from both parties. Pursuant to this Court's Rule 37.6, *Amici* attest that no counsel for a party had any role in authoring this Brief and no outside party has made a monetary contribution for its preparation or submission.

debate about the needs and autonomy claims of those suffering from intolerable pain and terminal illness – has so far persuaded thirty States to adopt legal rules that, in various ways, express the conviction that use of marijuana by a narrow class of seriously ill persons is not the sort of conduct that should give rise to criminal punishment or civil liability.

Although, as described herein, these State responses differ from one another in significant ways – some are avowedly symbolic; others establish intricate State-administered patient registration systems, and still others provide an affirmative defense against charges of possession or cultivation of small amounts of marijuana – this variety should not obscure fundamental points of commonality. First, these measures are concerned *exclusively* with individuals suffering from serious illness whose conditions are likely to benefit from marijuana – a class whose existence has been confirmed by the Institute of Medicine's authoritative study, and the contours of which research is defining with increasing precision. Such measures, which are consistent with the States' historic power to protect the health and well-being of their citizens, *see Huron Portland Cement Co. v. City of Detroit*, 362 U.S. 440, 442 (1960), have neither the purpose nor the effect of thwarting the Federal and State statutes that punish trafficking in marijuana or proscribe its possession for recreational use. Many of the measures viewed as the most aggressive are modest in actual operation – Alaska's program has an estimated 180 enrollees, and Oregon's has approximately 1,675 – and these same States, through their own courts, not only continue to punish those who engage in the marijuana trade, but have been vigilant in assuring that new protections for the grievously ill not become a shield for lawbreakers.

Nor are these developments the only significant changes in the background against which this case will be decided. Petitioner informs the Court, *see* Pet. Br. at 27 n.12, that the

U.S. Department of Health and Human Services will soon release *its* view of the scientific evidence concerning marijuana and health – as part of the disposition of a petition to reschedule marijuana, *see* 21 U.S.C. § 811(b). And as Petitioner's *Amici* repeatedly emphasize, the Institute of Medicine Report held out the hope that in coming years drugs derived from marijuana will be developed that will offer the same benefits with fewer adverse effects. *See* Br. *Amicus Curiae* of Family Research Council at 9.

This case, it should be underscored, does not call upon the Court to make an explicit *legal* judgment about any of these developments. Petitioner has not sought a declaration that any California law is unenforceable, *see* Pet. Br. at 9 n.6; 28 U.S.C. § 2403(b), and, as will be made clear below, it is not, in fact, necessary that the Court take cognizance of these developments to answer the narrow statutory question the case squarely presents. Rather, basic tools of statutory construction establish that the Court of Appeals was correct to hold that the equity jurisdiction conferred by 21 U.S.C. § 882 includes the full measure of traditional discretion, including authority to modify or dissolve injunctions when the public interest so requires. *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531 (1987).

Nor is it essential that the context be taken into account were the Court to undertake to resolve the much broader statutory question that the United States urges upon it. As will also be shown below, if the availability *vel non* of a necessity defense is to be taken up, ordinary statutory construction rules are also adequate in themselves to defeat Petitioner's argument that the Controlled Substances Act ("CSA") includes an (implicit) abrogation of the common law defense of medical necessity.

The evidence concerning scientific and legislative developments, we believe, does supply further reason for rejecting Petitioner's statutory argument – or, at least, for leaving the necessity question for a case in which it is squarely

presented. It is contrary to usual principles of judicial restraint, *see, e.g.*, *United States v. Raines*, 362 U.S. 17, 22 (1960), to resolve questions – whether, for example, an individual charged with criminal marijuana possession, *see* 21 U.S.C. § 844, may raise the defense of necessity – in a case arising out of a *civil* proceeding involving a *different* statutory provision, *see* 21 U.S.C. § 841(a)(1). And to the extent that Petitioner has evidence concerning conduct by *these particular Respondents* that is inconsistent with a claim of medical necessity, *see, e.g.*, Pet. Br. at 35 n.16, such allegations go to the propriety of the particular order issued in this case and cannot establish that there is *no set of facts* under which a necessity defense could be sustained. Indeed, though Petitioner has shown limited interest in having this case decided according to its particular facts – or in pressing for an injunction that better incorporates the safeguards it insists are necessary to prevent "abuse or diversion of the drug," *id.* at 26 n.11, it has had ample opportunity to do so – including in a still-pending Ninth Circuit appeal.

But if the Court is to venture an answer to the broadly-framed question, principles requiring that Federal statutes be construed so as to avoid difficult constitutional questions, and in a manner that takes due account of the States' role, argue strongly that a necessity defense has not been abrogated. *See Solid Waste Agency v. United States Army Corps of Engineers*, 121 S. Ct. 675, 683 (2001); *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 120 S. Ct. 1858, 1870 (2000); *Jones v. United States*, 526 U.S. 227, 239 (1999). First, the enforcement of laws criminally punishing marijuana possession would, in cases of suffering individuals with no effective therapeutic alternative, raise real and substantial constitutional questions. To the extent that an individual could show that he would suffer intolerable pain – or risk death – as a consequence of the government's refusal to allow him to possess marijuana, *Jenks v. Florida*, 582 So. 2d 676, 680 & n.4 (Fla. Ct. App. 1991), the Constitution's basic protections

against unjustifiable intrusions on individual liberty would be implicated. *See, e.g.*, *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Jacobson v. Massachusetts*, 197 U.S. 11, 24-30 (1905). The ultimate disposition of such a constitutional claim would then require assessment, *inter alia*, of the asserted governmental interests, the availability of less burdensome alternatives, and the existence of a practicable remedy. *See generally Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261 (1990).

This Court should construe the statute at issue in this case so as to postpone, rather than hasten, the day when such constitutional questions must be definitively resolved. Both the process of constitutional adjudication and that of self-government are advanced by allowing these complex questions – involving sensitive matters of public administration, science, and morality, as well as law – to continue to receive serious and thoughtful attention at the State level. *See Glucksberg*, 521 U.S. at 788-89 (Souter, J., concurring in judgment); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). Indeed, it is a testament to the approach that Justice Brandeis extolled that Petitioner's *Amici*, in the service of their argument for a maximal reading of the Federal statute, attempt comparisons based on the outcomes of the diverse policies pursued by the fifty States. *See* Br. *Amicus Curiae* of Institute on Global Drug Policy of the Drug Free America Foundation, *et al.*, App. 6.

In arguing for caution here and for respect for the good-faith efforts of the States to exercise their police powers in a manner that gives meaningful protection for significant personal liberty interests, we do not maintain that there is no limit to State "experimentation" under the Act – or that injunctive relief must be denied whenever there is a State policy supportive of a particular necessity claim. To the contrary, in settings where core congressional power is implicated and where the text and policy of the statute are clear and strong, the States must recede.

See 21 U.S.C. § 903 (providing for preemption when – but only when – there is a "positive conflict"). But in an instance where a State is acting carefully – on a matter of its core historic concern – and in a manner that respects clearly expressed congressional intent and is consistent with traditional constitutional and equitable limitations on the reach of the law, courts exercising Federal equity power should tread carefully, if at all.

ARGUMENT

I. Basic Statutory Construction Tools Establish the Correctness of the Appeals Court Decision.

In arguing for reversal, Petitioner urges this Court to make two separate and large interpretive leaps. The Court is asked to hold both: (1) that in conferring on Federal and State courts the power to enjoin violations of the CSA, *see* 21 U.S.C. § 882, Congress (silently) withheld the flexibility and discretion that are the acknowledged hallmark of the equity jurisdiction; *and* (2) that, by placing marijuana in Schedule I, the 91st Congress (by implication) abrogated a common law medical necessity defense. Ordinary statutory construction tools are sufficient in themselves to show the error of each proposition.

A. Congress Did Not Withhold Traditional Discretion.

Although Petitioner seeks to have this case decided on the broad ground that considerations of medical necessity are not cognizable in *any* proceeding, civil or criminal – in any way pertaining to a Schedule I substance – whether involving importation, distribution, or mere possession, *see infra*, the question most squarely presented is whether the grant of power contained in *section 882* should be construed as *requiring* Federal courts, sitting in equity, to enjoin any conduct that appears to be inconsistent with the substantive prohibitions of the CSA. As is shown convincingly and in finer detail in the Respondents' Brief, settled precedent directs a negative answer to that question.

In *Hecht Co. v. Bowles*, 321 U.S. 321, 330 (1944), *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 329-30 (1982), and *Amoco Production Co. v. Village of Gambell*, 480 U.S. 531 (1987), this Court affirmed that when a court exercises jurisdiction under a Federal statute providing for injunctive relief, it is presumed to have the full range of equity powers at its disposal, unless a contrary intent appears plainly in the text of the statute. *See Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946) ("the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied"); *Miller v. French*, 120 S. Ct. 2246, 2255 (2000) ("we should not construe a statute to displace courts' traditional equitable authority absent the 'clearest command'") (quoting *Califano v. Yamasaki*, 442 U.S. 682, 705 (1979)); *see generally Grupo Mexicano de Desarrollo S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 318 (1999).

Thus, rejecting arguments that Congress's enactment of the Emergency Price Control Act of 1942, 56 Stat. 23, had deprived a court of discretion to withhold injunctive relief, the *Hecht* Court explained:

> We are dealing here with the requirements of equity practice with a background of several hundred years of history . . . . The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mold each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims.

321 U.S. at 329-30. "[I]f Congress desired to make such an abrupt departure from traditional equity practice as is

suggested," *Hecht* continued, "it would have made its desire plain." *Id.* And *Romero-Barcelo* made clear that "[t]he grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances." 456 U.S. at 313; *see also Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc.*, 528 U.S. 167, 171 (2000) ("[d]enial of injunctive relief does not necessarily mean that the district court has concluded there is no prospect of future violations to deter").

Petitioner's argument against equitable discretion is considerably weaker than in those cases. Where this statute's terms provide simply that courts "shall *have jurisdiction* . . . to enjoin violations of [the CSA]," the law held insufficient to curb discretion in *Hecht* provided that upon a showing that the defendant "is about to engage in *any* . . . acts or practices [against the law], a permanent or temporary injunction, or other order *shall be entered* without bond." 56 Stat. 33 (emphasis added). *Cf. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("[T]he mandatory 'shall,' . . . normally creates an obligation impervious to judicial discretion.").[1/]

Nor would there be a plausible basis for believing that Congress intended for injunctions to be non-discretionary in this setting. First, ensuing history strongly suggests that Congress would have expected civil proceedings under the CSA to be a somewhat exotic alternative to the criminal prosecutions

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[1] And as Justice Rutledge observed – dissenting from a decision holding that the Emergency Price Control Act provisions governing the award of damages did not displace courts' power to award monetary restitution in their equitable discretion – "[i]t is not excessive to say that perhaps no other legislation in our history has equalled the Price Control Acts in the wealth, detail, precision and completeness of its jurisdictional, procedural and remedial provisions." *Warner Holding Co.*, 328 U.S. at 404 (Rutledge, J., dissenting).

that have always been the mainstay of the Act's enforcement.[2] Thus, this is not a case where the party enlisting the aid of equity would have no adequate remedy at law, nor is it an instance seeking prevention of an injury of truly irreparable character. *Compare Tennessee Valley Authority v. Hill*, 437 U.S. 153, 173-75 (1978) (concluding that only an injunction could vindicate the objectives of the Endangered Species Act), *with Romero-Barcelo*, 456 U.S. at 314 (noting that statutory purposes could be accomplished through the availability of "fines and criminal penalties"); *see also Friends of the Earth*, 528 U.S. at 171 (noting district court's reliance on civil penalties for deterrence).[3]

Of equal import, this case – involving, *inter alia*, the efforts of AIDS patients to secure a substance that the Institute of Medicine, in a recent, comprehensive study *commissioned by the United States*, pronounced to be "promising treatment," for their condition, *see infra* – would be an odd candidate for holding that Congress had, *sub silentio*, repudiated "the qualities of mercy and practicality" that this Court has identified as the "essence" of the equity jurisdiction. *Cf. Jacobson*, 197 U.S. at 38-39 (suggesting that in hypothetical case seeking to enforce compulsory vaccination statute against person whose "particular condition of . . . health or body" would make administration of the vaccine "cruel and inhuman," the judiciary

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[2] As the District Court noted, the entire thirty-year history of the CSA has yielded only five reported decisions involving section 882(a). *See United States v. Cannabis Cultivators Club*, 5 F. Supp. 2d 1086, 1104 (N.D. Cal. 1998).

[3] Indeed, though section 882(b) provides for "trial . . . by a jury in accordance with the Federal Rules of Civil Procedure" for those who violate injunctions, wholesale resort to that mode of proceeding would raise distinct constitutional questions. *See, e.g., International Union, United Mine Workers of Am. v. Bagwell*, 512 U.S. 821, 840 (1994) (Scalia, J., concurring).

would "be competent to interfere and protect the health and life" of "the individual concerned"); *cf. generally Chrysler Corp. v. United States*, 316 U.S. 556, 570 (1942) (Frankfurter, J., dissenting) ("A court of equity is not just an umpire between two litigants . . . the public interest is in its keeping as the conscience of the law. The circumstance that one of the parties is the Government does not in itself mean that the interest which it asserts defines and comprehends the public interest which the court must vindicate.").

B. The Statute Does Not Abrogate a Medical Necessity Defense.

Although this Court need not – and probably should not, *see infra* – decide the necessity defense question at the high level of abstraction that the United States demands, traditional statutory construction tools also establish that, if the question of abrogation is to be decided wholesale, it should be resolved for Respondents.

As Respondents point out, this Court has *never* construed a Federal statute as having entirely abrogated a common law justification defense, such as necessity or duress, *see United States v. Bailey*, 444 U.S. 394, 415-16 & n.11 (1980) (noting that "Congress in enacting criminal statutes legislates against a background of Anglo-Saxon common law," but holding that facts of that case would not support a necessity defense) (citing *Morissette v. United States*, 342 U.S. 246 (1952)), and such a drastic departure from settled legislative practice should not be found absent an unmistakably clear congressional statement. *See* Model Penal Code § 3.02(1)(c) (intent to abrogate justification defense should "plainly appear" in criminal statute).

Although Petitioner has argued that the text and structure of the CSA would satisfy any clear statement requirement, its near-exclusive reliance on Congress's placement of marijuana on Schedule I puts far greater weight on that particular

legislative action than it fairly may bear. In fact, the meaning Petitioner would have the Court ascribe to Congress's 1970 action is not the most plausible interpretation – let alone an inescapable one. Most fundamentally, contrary to Petitioner's drumbeat argument, *see, e.g.*, Pet. Br. at 14, 22, the placement *by Congress* of a substance in Schedule I *does not* equate automatically to a "*determination*" that marijuana "'has no currently accepted medical use in treatment in the United States,'" or has no "'accepted safety for use . . . under medical supervision.'" *Id.* (quoting 21 U.S.C. § 812(b)(1)(B) and (C)).

Rather, the text and structure of the statute make it plain that Congress *is not* bound by the same criteria as would be the Attorney General or the Drug Enforcement Agency in deciding a reclassification petition. Indeed, Congress has repeatedly affirmed this understanding, *see* H.R. Rep. No. 98-534, at 4 (1983), *reprinted in* 1984 U.S.C.C.A.N. 540, 543 (explaining legislation placing in Schedule I a drug – methaqualone – which previously had been approved by the FDA, by noting that "the [DEA] may not, in the absence of Congressional action, subject drugs with a currently accepted medical use in the United States to Schedule I controls"); *see also* Hillary J. Farias and Samantha Reed Date-Rape Prohibition Act of 2000, Pub. L. No. 106-172 (directing Attorney General, "notwithstanding sections [811(a), 811(b), 811(c) and 812)], to issue a final order placing GHB [gamma-hydroxybutyrate] in [Schedule I]").

National Organziation for Reform of Marijuana Laws (NORML) v. Bell, 488 F. Supp. 123, 139 (D.D.C. 1980), underscores this point. In that case, plaintiffs challenging the constitutionality of placement of marijuana on Schedule I argued strongly that it did not satisfy the statutory criteria. That contention, the district court explained, misconceived the statutory scheme: "Even assuming, arguendo, that marijuana does not fall within a literal reading of Schedule I," *NORML* explained, "[p]lacing marijuana in Schedule I furthered . . .

regulatory purposes of Congress," *id.* at 140; *see also id.* at 138-39 (explaining that "[t]he statutory criteria of Section 812(b)(1) are guides . . . but they are not dispositive" and noting Congress's "fear[]" that lighter penalties for marijuana "would create the impression that marijuana use was acceptable"). In sum, the core premise of Petitioner's argument – that Congress *actually* and *necessarily* resolved the question of medical necessity in 1970 – is a mistaken one. *Cf. Schiro v. Farley*, 510 U.S. 222, 236 (1994).[4]

Indeed, the contemporaneous history establishes with unusual clarity that the interpretation that the Petitioner insists is the *only* possible meaning of Congress's 1970 action – *i.e.*, that the placement of marijuana in Schedule I expressed an affirmative "declaration" or "determination" – is not really a tenable one. Recognizing that it was *not* in a position to make

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[4] The other arguments from the "statutory scheme" are no more persuasive. First, the existing statutory regime makes no provision for individuals who have in good faith exhausted all approved treatments, and its processes for rescheduling – which, in a prior instance, dragged on for nearly twenty-two years, *see Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*, 15 F.3d 1131 (D.C. Cir. 1994) – provide no meaningful alternative for individuals whose life expectancy is measured in months. As for the argument that the decision below "completely abandons any pretense of requiring [R]espondents to comply with" the "significant restrictions . . . [designed] to ensure a closed system of distribution," Pet. Br. at 24, 25, it appears that Petitioner did not propose specific limitations that might have enabled the injunction to operate in a manner that better approximated what Congress is claimed to have intended.

United States v. Kabat, 797 F.2d 580, 591-92 (8th Cir. 1986), cited at Pet. Br. at 20, is not helpful to Petitioner. The essence of the medical necessity defense is not that those asserting it "'disagree with the [government's policy] decisions,'" Pet. Br. at 20, but rather that they are "confronted with such a crisis as a personal danger, a crisis which did not permit a selection from among several solutions, some of which did not involve criminal acts," *Kabat*, 797 F.2d at 591 (citing *United States v. Seward*, 687 F.2d 1270, 1276 (10th Cir. 1986)).

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a judgment, the same Congress that went on to enact the CSA passed the Marijuana and Health Reporting Act, Pub. L. No. 91-296, requiring the Department of Health, Education, and Welfare to prepare a report on marijuana, *see* 1970 U.S.C.C.A.N. 418 (acknowledging the *lack* of "authoritative . . . information involving the health consequences of using marihuana"), and when the CSA was enacted, Congress accepted the interim written recommendation of HEW: that "marijuana be retained within schedule I" pending "the completion of certain studies now underway to resolve this issue," H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4579, 4629. Then, Congress created a Commission on Marihuana and Drug Abuse, which it "directed to prepare a report to guide Congress." Pub. L. No. 91-513, § 601. Whatever reasons subsequent Congresses may have had for not heeding that Commission's ultimate recommendation – *i.e.*, that possession and distribution of small amounts of marijuana be placed beyond the reach of the criminal law – such subsequent congressional inaction cannot retroactively convert the initial, pragmatic decision of 1970 into an affirmative "declaration" or "determination." *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 180-85 (1994).[5/]

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[5] The "sense of Congress" language inserted into the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, Div. F, 112 Stat. 2681, 2760-61, *see* Pet. Br. at 22, hardly fills the void. Whatever effect a court might give an *unambiguous* declaration that was passed in such marginal fashion, the legislation at issue states only that "*certain* drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision" (emphasis added) – not that *every* Schedule I substance meets that description – and then reaffirms Congress's commitment to the Federal Food, Drug and Cosmetic Act prohibition on "the *sale* of any unapproved drug, including marijuana," *id.* (emphasis added).

Congress's longstanding appropriations for the United States government to provide marijuana to a limited class of seriously ill individuals through its Compassionate Investigative New Drug ("CIND") Program further refute an argument from the words of section 812. Had Congress really "determined" that no individual could "safely" use marijuana "under medical supervision," it is doubtful that it would have provided the substance to the scores of individuals who have participated in that Program, under doctors' supervision, for nearly a quarter century. *See Kuromiya v. United States*, 78 F. Supp. 2d 367, 372 (E.D. Pa. 1999) (noting "obvious[] tension between the government's repeated statements that marijuana has not been proven to provide any beneficial results and its decision to continue supplying it to eight individuals for medical needs").[6]

Finally, the contention that there is any basic *logical* incompatibility between marijuana's placement on Schedule I and recognition of a medical necessity defense is further refuted

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Similarly, while Petitioner might have the Court believe that Congress has made a specific finding that marijuana use has "'a substantial and detrimental effect on the health and general welfare of the American people,'" Pet. Br. at 17 (quoting 21 U.S.C. § 801(2)), the actual statutory provision quoted does not mention marijuana, but refers generally to "[t]he illegal importation, manufacture, distribution, and possession and improper use of controlled substances." *Id.*; 21 U.S.C. § 801(1) (finding that "[m]any of [these same substances] . . . have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people").

[6] Indeed, the CIND program was initiated to settle a lawsuit filed by a patient who, based upon a showing of medical necessity, had been acquitted of unlawful cannabis cultivation in the District of Columbia. *United States v. Randall,* 104 Wash. D. Rep. 2249 (D.C. Super. 1976); *see also United States v. Burton,* 894 F.2d 188, 191 n.2 (6th Cir. 1990) (citing the existence of CIND Program as precluding defendant's asserting necessity defense and noting fact that "after this proceeding was begun, Burton became part of [the] program and now receives marijuana for his glaucoma under a physician's supervision").

by the decisions of State courts interpreting legislation that is identical in relevant respects to the Federal CSA. *See, e.g.*, *Jenks*, 582 So. 2d at 680; *Hawaii v. Bachman*, 595 P.2d 287 (Haw. 1979); *Idaho v. Hastings*, 801 P.2d 563 (Idaho 1990). Although these decisions do not control a Federal court's interpretation of the Federal statute, they further undermine any claim that the CSA language can *only* be read as abrogating a necessity defense.[7]

II. Principles of Judicial Restraint Counsel Strongly Against an Unduly Broad Reading of the Statute.

Even if traditional tools of statutory construction yielded a less definitive answer, however, fundamental rules of judicial self-restraint and federalism would argue against giving the CSA the sweeping construction that the Petitioner insists upon here. *See Raines*, 362 U.S. at 22 (noting that courts should avoid "premature interpretations of statutes in areas where their constitutional application might be cloudy").

A. This Case Is No Occasion for Announcement of a Broad Legal Rule.

At the outset, the question of the availability of a necessity defense to a *criminal* indictment is not even directly presented in this case, and while this proceeding involves charges of

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[7] Indeed, even the handful of State court decisions *declining* to allow a necessity defense have done so on grounds that *weaken* Petitioner's statutory argument. In these cases, as in *Burton*, courts have pointed to the existence of a (State) compassionate programs as foreclosing a defendant's establishing the prerequisite absence-of-lawful-alternatives element of the necessity defense – rather than holding that lawful possession of marijuana is incompatible *per se* with placement on the equivalent of Federal Schedule I. *See, e.g.*, *Kauffman v. Alabama*, 620 So. 2d 90 (Ala. Crim. App. 1992); *Minnesota v. Hanson*, 468 N.W.2d 77, 78 (Minn. Ct. App. 1991). *See generally* Marijuana Policy Project Report, *How Can a State Legislature Allow Patients to Use Medical Marijuana Despite Federal Prohibition?*, at L-1 to L-2 (Feb. 2001) ("MPP Report").

distributing marijuana, *see* 21 U.S.C. § 841, the grounds on which Petitioner would have the case resolved – that placement of marijuana in Schedule I conclusively eliminates a defense of medical necessity – would be far more broadly applicable to cases involving, for example, simple possession for use by an individual with a serious illness. In fact, as Petitioner recognizes, the criminal law of the State from which this case arises imposes criminal punishment for distribution – but not possession for therapeutic use – of marijuana; it continues to enforce that criminal statute, including against the sort of "buyers' club" to which Petitioner takes such strong exception, *California ex rel. Lungren v. Peron*, 59 Cal. App. 4th 1383, 1387 (1997) (closing San Francisco club under State law); *cf.* 21 U.S.C. § 844a (limiting penalties for first-time offenses involving possession of "personal use amounts" of certain substances).

In fact, Petitioner has maneuvered to have this case resolved on a very high plane of generality, declining the opportunity on remand to put evidence into the record that might have persuaded the District Court to exercise its discretion to retain a broader injunction. And though Petitioner underscores the significance of "restrictions . . . [designed] to ensure a closed system of distribution," Pet. Br. at 24, 25, no modification that might better serve the legislative purpose of preventing "abuse or diversion of the drug" was presented to the District Court. *See Gebser v. Lago Vista Indep. Sch. Dist.*, 524 U.S. 274, 289-90 (1998) (recognizing that "judicially implied system of enforcement" should track purpose and operation of "express system of enforcement").[8]

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[8] Similarly, evidence indicating that Respondents were making marijuana available to individuals without adequate proof of necessity, *see* Pet. Br. at 35 n.16, might support a claim that the modified injunction contains inadequate safeguards, but it is not an argument against recognizing *any* necessity exception. *Cf. Washington v. Harper*, 494 U.S. 210, 235 n.13

Finally, developments to which the Briefs of Petitioner and its *Amici* point actually highlight that the broad statutory question not only *need not* be decided in this case, but may be of declining significance. *Cf. Ticor Title Ins. Co. v. Brown*, 511 U.S. 117, 118 (1994) (*per curiam*) ("we have concluded that deciding this case would require us to resolve a constitutional question that may be entirely hypothetical, and we accordingly dismiss the writ as improvidently granted").

Thus, while *Petitioner's* arguments relate to "Schedule I substances" generally, this case in fact is concerned only with the therapeutic use of marijuana – a drug whose presence on Schedule I has an undeniably unique legislative history, *see supra*, one whose difference from other similarly classified substances has long been acknowledged, *see NORML*, including by those who administer the CSA, *see Kuromiya*, 78 F. Supp. 2d at 368-69 (discussing history of CIND program), and whose continued presence on that Schedule is the subject of a pending administrative proceeding. Indeed, Petitioner alerts the Court that the Department of Health and Human Services will soon release its evaluation of scientific evidence that others have found especially compelling.

And as Petitioner's *Amici* emphasize, the Institute of Medicine's study, while explicitly recognizing real therapeutic benefits that some derive from smoking marijuana, also predicts that the "'future of cannabanoid drugs lies not in smoked marijuana but chemically defined drugs,'" *see* Br. *Amicus Curiae* of Family Research Council at 9 (quoting IOM Report). Although the efficacy of such drugs may not be presumed – and their ultimate development will depend on market forces (and government willingness to allow research to proceed) – if the

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(1990) ("'[t]hat such a practice may take place in some institutions in some places affords no basis for a finding as to [the program at issue]'") (quoting *Parham v. J.R.*, 442 U.S. 584 (1979)).

optimism of *Amici* is well-founded, the significance of the issues presented for decision will diminish. *But cf.* IOM Report at 4 ("Although most scientists . . . agree that the pathways to cannabanoid research are clearly marked, there is no guarantee that the fruits of scientific research will be made available to the public for medical use.").[9]

B. A Restrained Construction Serves Important Constitutional Purposes.

1. This Case Implicates Issues of Constitutional Dimension.

To construe the statute as universally abrogating a medical necessity defense would run afoul of the rule that statutes should be construed – as the CSA surely may be in this case – so as to avoid, rather than invite, constitutional difficulty. *See Solid Waste Agency*, 121 S. Ct. at 683; *Vermont Agency of Natural Resources*, 120 S. Ct. at 1870; *Jones*, 526 U.S. at 239.

That rule of construction not only reflects separation of powers concerns – by presuming that legislators intend to honor their constitutional oaths – but, as this Court's decisions also recognize, it expresses a judgment that the *process of*

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[9] The advent of the fully effective alternatives would have obvious legal significance. Just as the defense to prison escape does not survive the disappearance of the condition creating the necessity, *see Bailey*, 444 U.S. at 415 (noting that escapee from prison fire is "'not to be hanged because he would not stay to be burnt,'" but holding that defense is available only to those who return) (quoting *United States v. Kirby*, 74 U.S. 482, 487 (1868)), the interest in allowing marijuana to be available for therapeutic purposes is premised on the *un*availability, for certain individuals, of an equally effective alternative.

On the other hand, the *potential* for such drugs has no relevance for the individuals whom Respondents and the State measures currently serve. *See* IOM Report at 7 ("It will likely be many years before a safe and effective can delivery system, such as an inhaler, is available for patients. In the meantime there are patients with debilitating symptoms for whom smoked marijuana might provide relief.").

constitutional adjudication itself benefits when complex questions are not prematurely resolved. *See Thompson v. Oklahoma*, 487 U.S. 815, 856 (1988) (O'Connor, J., concurring in judgment). Not only is it possible that the day for judicial resolution of an issue will not, in fact, arrive, *see id.* – legislatures might heed an emerging consensus or steer away from constitutionally sensitive approaches – but later deliberation can benefit from information about policy developments whose contours are not judicially foreseeable. *See Murray*, 492 U.S. at 14 (Kennedy, J., concurring in judgment) ("judicial imposition of a categorical remedy . . . might pretermit other responsible solutions being considered in Congress and state legislatures"); *cf. Arizona v. Evans*, 514 U.S. 1, 23 n.1 (1995) (Ginsburg, J., dissenting) ("We have in many instances recognized that when frontier legal problems are presented, periods of 'percolation' in, and diverse opinions from, state and federal appellate courts may yield a better informed and more enduring final pronouncement by this Court.").

These insights apply with special force in cases where the pertinent constitutional provision is open-ended and its interpretation dependent on discerning evolving societal standards and on ethical and scientific – as well as legal – considerations. Thus, in *Cruzan*, the Court, while recognizing that the interests involved were of constitutional magnitude, resisted announcing a comprehensive rule of law to govern the conditions under which life support from incompetent patients might be withdrawn, citing the "number of sources" available to States in considering such a "perplexing question with unusually strong moral and ethical overtones," 497 U.S. at 277.

Finally, reserving resolution of constitutional questions – in areas where both public opinion and relevant empirical facts are changing – can reinforce the premises expressed in the

Constitution's federal structure. Thus, in Justice Brandeis's classic formulation:

> To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.

New State Ice Co., 285 U.S. at 311 (Brandeis, J., dissenting); *see also San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 42 (1973) ("[t]he very complexity of the problems of financing and managing a . . . public school system suggests that there will be more than one constitutionally permissible method of solving them") (internal citation and quotation omitted).

Encouraging deliberation at the State level on difficult questions – including those of constitutional magnitude – is important to the process of self-government. *See FERC v. Mississippi*, 456 U.S. 742, 790 (1982) (O'Connor, J., concurring in part and dissenting in part) ("Citizens . . . cannot learn the lessons of self-government if their local efforts are devoted to reviewing proposals formulated by a faraway national legislature."); William H. Rehnquist, 1998 Year-End Report of the Federal Judiciary, 11 Fed. Sent. R. 134, Nov.-Dec. 1998 (noting that the "pressure in Congress to appear responsive to every highly publicized social ill . . . needs to be balanced with an inquiry whether . . . we want most of our relationships decided at the national rather than the local level").

These considerations played a central role in the Court's recent decisions involving assertions of constitutional right by (and on behalf of) individuals suffering from terminal illness. Thus, in *Cruzan*, Justice O'Connor's concurring opinion explained:

> [N]o national consensus has yet emerged on the best solution for this difficult and sensitive problem. Today we decide only that one State's practice does not violate the Constitution; the more challenging task of crafting appropriate procedures for safeguarding incompetents' liberty interests is entrusted to the "laboratory" of the States, in the first instance.

497 U.S. at 292 (citing *New State Ice Co*).

And the various opinions in *Glucksberg* and *Vacco v. Quill*, 521 U.S. 793 (1997), approached the assertions of constitutional right in similar fashion, recognizing that the issues in these cases touched on fundamental liberty interests, but that many of the questions of constitutional relevance – bearing on whether a right could be recognized, whether an asserted State interest could be accomplished through less invasive means, and whether a practicable remedy could be devised – were not yet amenable to definitive resolution. *See Glucksberg*, 521 U.S. at 745 (Stevens, J., concurring in judgment) (noting that "[a]voiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly "[a]t the heart of [the] liberty" interest protected by the Constitution) (citation omitted); *id.* at 792 (Breyer, J., concurring in judgment) ("were a state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life[,]" the constitutional concerns "would be more directly at issue"); *see generally id.* at 737 (O'Connor, J., concurring) (noting "extensive and serious evaluation" of issues by States).

Whether or not these recent precedents are read as *establishing* that a seriously ill person has a right to access to marijuana or any other particular medically necessary therapy, the evidence increasingly confirms that there is an identifiable – but limited – class of very ill people for whom marijuana *does* offer real and unique medical benefits, *i.e.*, for whom the predicament hypothesized in Justice Breyer's opinion is a real

one. The interests of such individuals, whom cannabis enables to manage what would be "otherwise unavoidable physical pain" and other serious health- and life-threatening symptoms, are "of constitutional dimension[]." *See United States v. Randall*, 104 Wash. D. Rep. 2249, 2253 n.29 (D.C. Super. 1976) ("a law which apparently requires a person to submit to deteriorating health without proof of a significant public interest to be protected raises questions of constitutional dimensions"); *see also Jacobson*.[10/] It would be unfortunate to require courts and legislatures – as they would have to in the absence of any cognizable necessity defense – to consider these questions primarily through a constitutional lens. *See Glucksberg*, 521 U.S. at 788-89 (Souter, J., concurring in judgment).

Thus, the Institute of Medicine Report concluded that cannabis is "promising for treating wasting syndrome in AIDS patients" and that for them and other "patients . . . who are undergoing chemotherapy and who suffer simultaneously from severe pain, nausea, and appetite loss, cannabinoid drugs might offer broad-spectrum relief not found in any other single medication," IOM Report at 177, and within that group, "[t]here will likely always be a subpopulation of patients who do not respond well to other medications," *id.* at 3-4; *see also id.* at 154 ("for patients for whom standard antiemitic therapy is ineffective and who suffer from debilitating emisis," the "harmful effects of smoking marijuana for a limited period of time might be outweighed by the antiemitic benefits"); *cf.* S.J.

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[10] Significantly, the primary evidence of marijuana's therapeutic value is not as a *cure*, but rather as enabling individuals suffering from serious illness to better respond to and tolerate potentially life-saving conventional treatments. That point is critical in distinguishing the legal claims in cases such as this one from those in *United States v. Rutherford*, 442 U.S. 544 (1979), and *Quill*, where there was a substantial interest in protecting individuals from harm and in encouraging them to pursue promising modes of treatment and pain relief.

Gould, *It Works Like a Charm*, N.Y. Times, May 4, 1993 (describing successful use of marijuana in course of treatment for abdominal mesothelioma after "absolutely nothing in the available arsenal of anti-emetics worked at all").

2. In Diverse and Appropriate Ways, States Have Sought to Recognize and Safeguard These Interests.

There is growing sentiment – informed by this and other research, as well as by greater discussion of the dilemmas confronting individuals with terminal illness – that it is wrong to punish individuals who are seriously ill for availing themselves of relief from pain and other debilitating symptoms. As the Institute on Medicine summarized, "public support for patient access to marijuana for medicinal use appears substantial; public opinion polls taken during 1997 and 1998 generally report 60-70 percent of respondents allowing medicinal use of marijuana." IOM Report at 18. Similarly, a 1999 Gallup Survey showed that 73% favored "making marijuana legally available for doctors to prescribe in order to reduce pain and suffering." MPP Report at D1; *see also* Robert J. Blendon & John T. Young, *The Public and the War on Illicit Drugs*, 279 JAMA 827 (1998) (reporting analysis of public opinion surveys concerning medical use of marijuana).[11/]

These sentiments have been expressed not merely in public opinion surveys, but in legislation and popular initiatives at the State level. *Compare Penry v. Lynaugh*, 492 U.S. 302, 333-35

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[11] The Institute on Medicine's report also addressed the empirical evidence bearing on other questions that figure in debates over allowing access to marijuana for medical purposes, finding, for instance, that there is "no convincing data to support th[e] concern that sanctioning medical use of marijuana might increase its use among the general population," *id.* at 104 and that "there is no evidence that the medical marijuana debate has altered adolescents' perceptions of the risks associated with marijuana use," *id.*

(1989) ("The clearest and most reliable objective evidence of contemporary values is the legislation enacted by the country's legislatures . . . . The public sentiment expressed in . . . polls and resolutions may ultimately find expression in legislation, which is an objective indicator of contemporary values upon which we can rely.").[12]

There are now thirty States that have, in some fashion, recognized the interests of those for whom marijuana provides needed relief. *Cf. Cruzan*, 497 U.S. at 282 n.10 ("important individual interests should [not] be afforded less protection simply because the [State] government" is the party defending them). As would be expected in a federal system – one in which public health has been primarily the concern of the States, *see Jacobson* – the various States that have undertaken to recognize and safeguard these rights have done so in very different ways. In some States, as noted above, judicial decisions have recognized a narrow medical necessity defense when individuals using marijuana therapeutically have been prosecuted for violating drug laws. *See California v. Trippet*, 56 Cal. App. 4th 1532 (1997); *Jenks*, 582 So. 2d at 680; *Hawaii v. Bachman*, 595 P.2d 287 (Haw. 1979); *Idaho v. Hastings*, 801 P.2d 563 (Idaho 1990).

Fourteen others currently have statutes authorizing the administration of "therapeutic research programs," whereunder patients meeting narrowly circumscribed criteria could obtain

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[12] Although *Penry* and *Thompson* involved the Eighth Amendment's Cruel and Unusual Punishments Clause, this Court's cases have noted a substantial convergence between that prohibition and that of the Due Process Clause. *See Whitley v. Albers*, 475 U.S. 312, 327 (1986); *cf. Jacobson*, 197 U.S. at 39 ("cruel and inhuman in the last degree" to enforce compulsory vaccination statute against person with potentially lethal reaction); *Robinson v. California*, 370 U.S. 660, 667 (1962) ("Even one day in prison would be a cruel and unusual punishment for the 'crime' of having a common cold.").

small quantities of marijuana from private physicians and the States themselves – although these programs have foundered as a practical matter.[13] Four other States – Alaska, Iowa, Montana, and Tennessee – have amended their statutes so as to place marijuana on a schedule that recognizes its therapeutic use.

Numerous other States have enacted more frankly symbolic legislation,[14] and legislatures in six States – Missouri, Michigan, New Hampshire, California, Washington, and New Mexico – have passed non-binding resolutions urging the Federal government to make marijuana available by prescription. *See, e.g.*, Mo. Sen. Con. Res. 14 (1994); Cal. Sen. Joint Res. No. 8 (Sept. 2, 1993).

Far more attention has been given to the more thorough reforms passed in eight States (seven by popular initiative) in recent years – Alaska, California, Colorado, Hawaii, Maine, Nevada, Oregon, and Washington. These laws either provide an exemption from prosecution or supply an affirmative defense to (State) charges of possession of up to a small amount of

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[13] *See, e.g.*, Ala. Code § 20-2-110; Ga. Code Ann. § 43-34-120; 720 Ill. Comp. Stat. 550/11; Mass. Gen. Laws ch. 94D §1; Minn. Stat. § 152.21; N.J. Stat. Ann. § 26:2L; N.Y. Pub. Health §§ 3328, 3397; R.I. Gen. Laws § 21–28.4-1; S.C. Code Ann. § 44-53-610; Tex. Health & Safety Code Ann. §§ 481.111, 481.201-205; W. Va. Code § 16-5A-7; *see also* Wash. Rev. Code § 69.51; N.M. Stat. Ann. § 26-2A. In almost every State, the efficacy of these programs was hampered by the cumbersome and expensive Federal review process. California has recently undertaken the most ambitious State research program. *Amicus* Vasconcellos was the sponsor of S.B. 847, which appropriated $3 million for the California Center for Medicinal Cannabis Research. *See* Cal. Health & Safety Code § 1136.9.

[14] A number have laws provide for changes in State treatment of marijuana that take effect when – but only when – *Federal* law changes. *See, e.g.*, Conn. Gen. Stat. §§ 21-a-246, 21a-253; Mont. Code Ann. § 50-32-222(7); N.H. Rev. Stat. Ann. § 318-B-9; Tenn. Code Ann. § 68-52-101; Va. Code Ann. § 18.2-250.1; Vt. Stat. Ann. tit. 18 § 4471; Wis. Stat. § 46.60.

marijuana for individuals suffering from certain defined medical conditions who have been advised by their doctor that they are likely to benefit from marijuana. Five of the States provide for registration processes for those individuals, *see* Alaska Stat. § 17.37; Haw. Rev. Stat. § 329; Or. Rev. Stat. § 475.300; Colo. Const. amend. 20; Nev. H.B. 121 (proposed), and three (Alaska, Hawaii, and Nevada) make registration a mandatory precondition to receiving the law's protections.[15/]

The caricatures and anecdotes offered by Petitioner's *Amici* notwithstanding, these recent measures, while more aggressive than prior efforts, remain confined to the area where claims of individual right are most compelling, where traditional State powers and responsibilities are at their apex, and where legitimate Federal interests are most attenuated: relieving the threat of (State) penalties for possession of small amounts of marijuana by individuals suffering from debilitating medical conditions.

Thus, these programs remain generally modest in size and are being administered in good faith, and with due respect for the laws prohibiting distribution – and possession – of marijuana for any other, non-medical reason. *See, e.g.*, *Oregon v. Arana*, 998 P.2d 688, 689 (Or. Ct. App. 2000) (affirming marijuana dealer's conviction for "the manufacture, delivery, and possession of a schedule I controlled substance," Or. Rev. Stat. § 475.992); *see also California v. Rigo*, 69 Cal. App. 4th 409 (1999) (declining to give broad interpretation to Proposition 215 protection); *Trippet*, 56 Cal. App. 4th at 1550 (same). Most provide for active monitoring and control by public health officials, and the evidence shows that they are resorted to by doctors in a conscientious and professional

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[15] Colorado and Nevada voters approved constitutional amendments on November 7, 2000. Their legislatures are now considering the implementing legislation.

manner. *See Washington v. Harper*, 494 U.S. 210, 223 (1990) ("we will not assume that physicians will prescribe . . . drugs for reasons unrelated to the medical needs of the patients; indeed, the ethics of the medical profession are to the contrary"). Their effects are being carefully studied and debated at all levels of State government. *See, e.g.*, Report of Maine Attorney General's Task Force On Medical Marijuana (Sept. 13, 2000).

For example, in Oregon, the Health Division of the State Department of Health and Human Services has taken an active role. Some 1,700 patients have registered, as a result of recommendations by 515 doctors. In Alaska, there are 180 patients, and in Maine, 250 participants. *See* MPP Report App. F. The petitions of patients and caregivers to have different conditions recognized as eligible have been carefully considered. *See id.* at F-5, F-10.[16]

Indeed, many – including those in the law enforcement community – who expressed apprehension have been favorably impressed by the good faith with which these have been implemented. *See* Michael Pollan, *Living with Medical Marijuana*, N.Y. Times Magazine, July 20, 1997.

These measures not only fulfill the States' important role of protecting the fundamental rights of the individuals within their jurisdiction, but they provide a body of experience that can inform future deliberations in the political and judicial branches at every level. Indeed, it is a testament to the constructive and constitutionally appropriate role the States are playing that

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[16] The anecdotal focus on California, *see* Family Research Council Br. at 17-20, while understandable at one level, is, in an important sense, misleading. California's law is broader than those of other States, and has so far provided for a less active role for public health officials. *Cf. California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980). Thus, concerns that may have some arguable force with respect to California simply have no relevance to the other jurisdictions.

Petitioner's *Amici* have included an Appendix to their brief that attempts to use comparative statistics from the fifty States to show that allowing limited access to cannabis for those with certain grave medical conditions will weaken young people's resolve to refrain from experimentation with recreational drugs. Although we doubt both the premises of that argument and the probative weight of those crude statistics, *see supra* n.11, the ability to make such comparisons and argue about their legal and policy implications is precisely the sort of "happy incident" of federalism that Justice Brandeis's opinion celebrated.

III. Courts May Consider Legitimate State Interests In Exercising Equitable Discretion.

In addition to the States' roles as constituents of the federal system, the measures discussed implicate their traditional sovereign interests and responsibilities, as well. *See Solid Waste Agency*, 121 S. Ct. at 683; *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 544 (1994) ("[f]ederal statutes impinging upon important state interests cannot . . . be construed without regard to the implications of our dual system of government") (internal citation and quotation omitted); *Parker v. Brown*, 317 U.S. 341 (1943) (interpreting Sherman Act so as not to reach anti-competitive conduct sanctioned by State law). Although the District Court did not rely on State interests in deciding on the scope of injunctive relief ordered in this case, an equity court's power to vindicate the "public interest" includes the power – and responsibility – to take account of legitimate State interests, as well. Nothing in the text of § 882 – or the structure of the Act as a whole – requires otherwise.

While an equity court must give effect to statutory policies, the law is clear that the policies expressed in any one Federal statute do not always define "the public interest." *See Village of Gambell*, 480 U.S. at 545-46 (while the "statutory interest in preservation of subsistence resources is *a* public interest," it does not necessarily "supersede all other interests that might be

at stake"); *Chrysler Corp.*, 316 U.S. at 570 (Frankfurter, J., dissenting) ("The circumstance that one of the parties is the [United States] Government does not in itself mean that the interest which it asserts defines and comprehends the public interest which the court must vindicate.").

In fact, "[w]hen the frame of reference moves . . . to a system of Federal courts representing the Nation, subsisting side by side with 50 state judicial, legislative, and executive branches, appropriate consideration must be given to principles of federalism in determining the availability and scope of equitable relief," *Rizzo v. Goode*, 423 U.S. 362, 379 (1976).

Although the CSA no doubt restricts the range of measures that States may implement, it is not plausibly read as divesting States of all power to pursue measures narrowly targeted to serious local public health problems. To the contrary, in statutory language no less emphatic than any relied on by Petitioner here, the Act expressly disclaims an interest in "occupy[ing] the field," providing only those State laws that are in "positive conflict" with the Federal statute should yield. 21 U.S.C. § 903.

And this Court's decisions have long recognized the preeminent role of the States in matters of public health.

> The safety and the health of the people of Massachusetts are, in the first instance, for that commonwealth to guard and protect. They are matters that do not ordinarily concern the national government. So far as they can be reached by any government, they depend, primarily, upon such action as the state, in its wisdom, may take.

Jacobson, 197 U.S. at 38; *see United States v. Lopez*, 514 U.S. 549, 566 (1995) ("The Constitution . . . withhold[s] from Congress a plenary police power that would authorize enactment of every type of legislation."); *Davies Warehouse Co. v. Bowles*, 321 U.S. 144, 154 (1944) ("At a time when great measures of concentration of direction are concededly

necessary, it may be thought more farsighted to avoid paralyzing or extinguishing local institutions which do not seriously conflict with the central government's place.").[17]

As described above, many States have pursued policies that seek to protect and secure the medical needs of seriously ill individuals, without compromising the objectives of preventing abuse and diversion that Petitioner identifies as at the core of the Federal statutory concern. These initiatives pose no "serious" conflict with Federal law, and neither the substantive nor the jurisdictional provisions of the Act should be construed in a manner that might lead to their being extinguished.

CONCLUSION

For the reasons set forth above – and those presented by Respondents – *Amici* request that the judgment of the Court of Appeals be affirmed.

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[17] Indeed, the measures discussed herein reflect a further reality: that although Federal law may aspire, in Petitioner's terms, to a "closed system," marijuana remains widely enough available that individuals whose medical needs are grave enough to lead them to run the gauntlet of potential punishment are likely to be able to obtain it. Accepting that reality, the States must be accorded some latitude to decide that these individuals and the public generally will be better served by a regime that maximizes the involvement of physicians and State health officials and minimizes any role for those who traffic in illicit drugs.

Respectfully submitted,

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In the Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF EDWARD NEIL BRUNDRIDGE, IMA CARTER, REBECCA NIKKEL AND LUCIA Y. VIER AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Amici curiae, Edward Neil Brundridge, Ima Carter, Rebecca Nikkel and Lucia Y. Vier (collectively, the "Members"), are parties-in-intervention in the underlying actions from which the writ of *certiorari* arises.[1] They are members of the cannabis cooperatives, including respondent cooperative, against which the government sought injunctive relief. The Members intervened below as defendants. They answered, invoking the common law defense of necessity, and filed counterclaims-in-intervention seeking a declaration of their fundamental right to be free from governmental interdiction of their personal, self-funded medical decisions, in consultation with their physicians, to alleviate their suffering through the only effective treatment available to them: cannabis.

The Members suffer from chronic pain that seriously diminishes their quality of life. To obtain the only effective medical treatment available to alleviate their pain and allow them to function, the Members joined the cooperative associations that were formed after the passage in California of the Compassionate Use Act of 1996 (Calif. Health & Safety Code § 11362.5). The state statute sought to ensure that seriously ill Californians would have the right to obtain and use cannabis for medicinal purposes. The cooperatives are the only available legal source of safe and affordable cannabis to the Members.

As members of California cannabis cooperatives, the Members have an interest in the affirmance of the court of appeals' decision upholding the availability of the medical necessity defense in any action by the government to enforce

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[1] The parties have consented to the filing of this brief, and the written consents of each of their counsel of record are filed with this brief. Counsel for a party did not author this brief in whole or in part, and no person or entity, other than the *amici curiae* or their counsel, made a monetary contribution to the preparation or submission of the brief.

the Controlled Substances Act (21 U.S.C. § 801 *et seq.*) against respondents or themselves. In response to the government's enforcement action, the Members intervened and have invoked the defense of necessity in their answer. Like respondents, the Members argued below that distribution of cannabis to members of California cooperatives under circumstances that meet the common law standard of necessity articulated in *United States v. Aguilar*, 883 F.2d 662, 692 (9th Cir. 1989), may not be enjoined under the Controlled Substances Act. The Members urge the Court to affirm the court of appeals' judgment.

Although their constitutional claim is not before the Court, the Members also have an interest in ensuring that they have an adequate opportunity to present that claim below if necessary.[2] The question presented by the petition for *certiorari* is whether a medical necessity defense is available to respondents under the Controlled Substances Act. Should the Court reverse the court of appeals' ruling that the defense is available, resolution of this question of statutory interpretation would not prevent the Members from presenting their constitutional claim in light of a fully developed record. *See Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997).

To establish their constitutional claim, the Members intend to present evidence that the fundamental right they assert is deeply rooted in this Nation's history and tradition. In a related appeal, the court of appeals has ordered that the Members be allowed to do so.[3] The government has not

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[2] In this regard, the government has argued in the past and may argue again below—although it does not do so here—that respondents do not have standing to assert the Members' fundamental constitutional right as set forth in their counterclaims below.

[3] Pursuant to Federal Rule of Evidence 201, the Members request that the Court take judicial notice of the court of appeals' decision on May 10, 2000 in appeal nos. 99-15838, 99-15844 and

(footnote continued)

sought review of that ruling and thus the outcome of its challenge here to the appellate court's construction of the Controlled Substances Act cannot avert district court consideration of the constitutional issue presented by the Members' counterclaim.

SUMMARY OF ARGUMENT

The Court is being asked to decide whether a common law necessity defense is available in a civil enforcement action under the Controlled Substances Act. This brief describes the constitutional right to be free from governmental intervention in their medical treatment that the Members have asserted in the underlying actions. The existence of this right is an additional and compelling reason for this Court to rule that in enacting the Controlled Substances Act, Congress did not intend to preclude respondents' invocation of the necessity defense in this context.[4] The Members also ask the Court to ensure that its disposition of the present appeal not restrict the Members' ability to present their constitutional claim for a hearing in the district court on a fully developed record.

The Members' constitutional claim satisfies the two-pronged test adopted by the Court in *Washington v. Glucksberg*, 521 U.S. at 720-21. The first step focuses on consideration of the nature of the interests that the Due Process Clause protects: namely, fundamental rights and liberties that are "'deeply rooted in this Nation's history and tradition.'" *Id.* (quoting *Moore v. East Cleveland*, 431 U.S.

99-15879, reversing the district court's dismissal of the Members' counterclaim.

[4] Under well-settled rules, Congress is presumed to have enacted legislation in accordance, rather than in conflict, with constitutional guarantees (*United States v. X-Citement Video, Inc.*, 513 U.S. 64, 73 (1994)), and the preferred construction of a federal statute is therefore one that avoids potential constitutional infirmity. *Id.* at 78.

494, 503 (1977) (plurality opinion)). This brief previews the types of evidence that the Members intend to offer below if necessary, to establish the deep and important historical roots for their fundamental right.[5] The second step in the substantive due process inquiry involves a formal prerequisite: that the asserted fundamental liberty interest be "careful[ly]" and narrowly described. *Id.* at 721. The right asserted in the Members' counterclaim satisfies this requirement. The Members assert the right to be free from governmental interdiction of their personal, self-funded medical decision, in consultation with their physicians, to alleviate their suffering through the only effective treatment available to them.

Finally, this brief addresses the government's argument—relegated to a footnote (*Brief for the Petitioner* ("Brf.") at p. 25, fn. 14) —that such a fundamental right does not exist. The government argues that the recognition of such a right is foreclosed by cases holding that individuals have no right to require a federal agency to reclassify a drug (*Carnohan v. United States*, 616 F.2d 1120 (9th Cir. 1980)) or to have a particular type of treatment. *Rutherford v. United States*, 616 F.2d 455 (10th Cir. 1980). The government's authorities confirm, however, that the right to decide whether or not to have effective medical treatment at all is in fact fundamental. *Id.* at 457. Moreover, the relief the Members seek does not require the government to take any positive action. Instead, the Members ask that the government "leave them alone" and that they be permitted to act on their doctors' recommendations regarding the only available treatment that has proven effective for them.

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[5] This brief discusses the Nation's history and traditions supporting the right to bodily integrity and to be free from pain (pp. 9-14 *infra*) and the sanctity of the physician-patient privilege (pp. 14-17 *infra*). As part of the proof to be adduced in the district court, the Members also intend to show the long-accepted practice until the 1940s of using cannabis as a medicine. *See* Joint Appendix, Declaration of Lester Grinspoon, M.D., etc., at 122-125 (detailing history and tradition of therapeutic uses of cannabis).

STATEMENT OF FACTS

The Members are seriously ill individuals, and cannabis is the only effective medical treatment available to alleviate their pain. The Counterclaim[6] seeks (1) a declaration of the Members' fundamental right under the Fifth Amendment to be free from governmental interdiction of their personal, self-funded medical decisions to take the only effective legal medication available to relieve their own pain and suffering, to obtain their personal physicians' recommendations for appropriate medical care for serious illnesses and injuries, and to take advantage of available medications for such conditions as recommended by their personal physicians and (2) a declaration that the government cannot seek enforcement of the Controlled Substances Act against the Members or the cooperatives because it would violate the Members' fundamental right.[7]

As alleged in the Counterclaim, Lucy Vier, Becky Nikkel, Ed Brundridge and Ima Carter suffer from serious medical conditions, will suffer imminent harm if denied cannabis, need cannabis for the treatment of a medical condition or to alleviate the medical condition or symptoms

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[6] Pursuant to Federal Rule of Evidence 201, the Members request that the Court take judicial notice of each Counterclaim-in-Intervention (the "Counterclaim") (filed October 2, 1998), each Answer-in-Intervention (filed October 2, 1998), and the Members' motion for leave to intervene and the memorandum of points and authorities and the Members' declarations in support thereof (filed August 14, 1998), which were filed in the United States District Court for the Northern District of California in action nos. 98-00085, 98-00086, 98-00087, 98-00088 and 98-0245.

[7] The Counterclaim also seeks a preliminary and permanent injunction restraining the government from interfering with the Members' exercise of their fundamental right and from attempting to enjoin the cooperatives from providing the Members or their primary caregivers with safe and affordable cannabis for personal medicinal use by the Members upon a physician's recommendation as permitted by the Compassionate Use Act of 1996.

associated with it and have no legal alternative to cannabis for the effective treatment of their condition. Each has tried other legal alternatives to cannabis but has found that they are ineffective in treating their condition or result in intolerable side effects.

The Members' doctors have determined that cannabis would be beneficial to their health and have recommended its use. In each case, the physician's recommendation conforms to California's Compassionate Use Act.

Lucy Vier has been diagnosed with terminal squamous cell cancer. She has undergone radiation and chemotherapy treatments, but they have caused her to experience nausea and made it almost impossible for her to taste food. Ms. Vier's doctor accordingly recommended that she use cannabis to stimulate her appetite. Because of her small physique (she is approximately four feet eleven inches tall and weighs eighty-seven pounds), it is crucial that Ms. Vier maintain her weight. She has found that cannabis is effective to stimulate her appetite. Without cannabis, Ms. Vier is unable to eat enough food to maintain her health.

For these reasons, in the opinion of Ms. Vier's treating physician (as well as herself), the use of cannabis is a medical necessity. No known traditional medicines stimulate her appetite effectively. If she were unable to use cannabis, she will lose weight rapidly, and her day-to-day pain will increase. She also believes that without cannabis, she would not be able to survive as long as her doctor's prognosis.

Becky Nikkel has fibromyalgia and multiple sclerosis. These conditions cause her to experience severe, painful muscle spasms. She experiences pain on a daily basis, and at times, it can be continuous. Ms. Nikkel has tried many conventional treatments and medicines, but they have been ineffective or caused allergic reactions. For example, upon the recommendation of her doctor, Ms. Nikkel tried baclofen, but that caused her legs to become so weak that she could not walk. Another conventional medication caused a

severe allergic reaction that progressed to anaphylactic shock and was nearly fatal.

Ms. Nikkel's doctor recommended cannabis as the only medicine that effectively and safely alleviates the pain caused by her muscle spasms. The absence of other medical alternatives for relief of her pain makes using cannabis a medical necessity for Ms. Nikkel.

Ed Brundridge suffers from severe arthritis in the right knee, which causes him extreme pain and inability to walk unaided by a cane. He also suffers from loss of appetite due to anxiety and depression. To alleviate pain, Mr. Brundridge has tried many traditional medicines, such as ibuprofen. All of them, however, either were ineffective or caused him to experience an allergic reaction. Moreover, he is unable to take many traditional pain relievers due to liver damage as a result of Hepatitis C and peculiar addiction risks he faces as a recovering alcoholic and drug abuser.

Mr. Brundridge's doctor recommended cannabis as a legal medical alternative to relieve his pain caused by the swelling in his knee and to stimulate his appetite. Cannabis is the only medicine that he has used that effectively alleviates the pain of his arthritis and counteracts the dietary effects of his anxiety and depression. Obviously, aware of his patient's background of addiction, Mr. Brundridge's doctor recommended cannabis based on his knowledge that it is not addictive. Without cannabis, Mr. Brundridge believes he would not be alive today.

Ima Carter has congenital scoliosis, fibromyalgia and cervical nerve damage. These conditions cause her severe back and head pain. Ms. Carter has tried numerous traditional medicines for these conditions, none of which has been effective. Cannabis is the only drug that she has used that has dulled or stopped the pain. She was once forced to go without cannabis temporarily. During that time, Ms. Carter was completely disabled by pain and unable to leave her bedroom. She now uses cannabis on the recommendation of her doctor. Cannabis is the only effective treatment available to alleviate her pain. If there

were anything Ms. Carter could do to relieve her pain other than using cannabis, she would do it.

If respondents and the other defendant cooperatives below are prevented from distributing cannabis to persons such as the Members, who satisfy the criteria for medical necessity, these seriously ill individuals will be unable to obtain cannabis legally or safely. The Members thus would suffer a special harm to their privacy interests and doctor relationships as a result of the attempted governmental intrusion. If the government's challenge to the modification of the preliminary injunction is upheld, the Members will be unable not only to speak freely with their doctors about their conditions and medical needs, but also to act on their doctors' recommendations as to the only medication that effectively alleviates their pain or stimulates their appetite: cannabis.

ARGUMENT

I. The Members Have a Constitutional Right to Be Free from Governmental Interdiction of Their Personal, Self-Funded Medical Choices, in Consultation with Their Personal Physicians, to Alleviate Their Suffering through the Only Effective Treatment Available for Them.

The Members advocate a narrow substantive due process right: the right to treat themselves and to be free from pain by using the only effective medical treatment available to them pursuant to their physicians' recommendations. To achieve a constitutional dimension, a claimed "fundamental" right must be "implicit in the concept of ordered liberty." *Palko v. Connecticut*, 302 U.S. 319, 325 (1937). The interest asserted must be, "'deeply rooted in this Nation's history and tradition,' [*Moore*, 431 U.S. at 503] . . . and 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if [it] were sacrificed,' [*Palko*, 302 U.S.

at 325]." *Washington v. Glucksberg*, 521 U.S. at 720-21. [8] An analysis of the history and tradition of a right "tends to rein in the subjective elements that are necessarily present in due-process judicial review." *Id.* at 722. As outlined below, this Nation's history and tradition of protecting the individual's right to privacy and bodily integrity and of safeguarding the integrity of the physician-patient relationship demonstrate that the right claimed by the Members is "fundamental" within the meaning of the Due Process Clause.

A. The right to bodily integrity and to be free of pain.

The Members' asserted fundamental right has deep roots in our Nation's history and legal tradition of permitting decisions about one's body to be made free from governmental intervention. The right articulated by the Members is concomitant with the established rights to bodily integrity and to be free of pain.

The right to be free of government intrusion with respect to one's body has roots in natural law principles and the philosophy of individual autonomy. *See* Mill, *On Liberty*, 60-69 (Penguin Books 1985) (1859) (concluding that "[o]ver himself, over his own body and mind, the individual is sovereign"). United States legal precedent in the past century has consistently upheld legal protection for this individual right.[9] In fact, the origin of this precedent in the

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[8] In *Washington v. Glucksberg*, the Court considered whether the State of Washington's prohibition against physician-assisted suicide violated substantive due process guarantees. In concluding that it did not, the Court reviewed the 700-year history of suicide and assisted suicide under the Anglo-American common law tradition. 521 U.S. at 711. In addition, the Court considered that, "[t]hough deeply rooted, the States' assisted-suicide bans ha[d] in recent years been reexamined and, generally, affirmed." *Id.* at 716.

[9] *See, e.g., Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 281 (1990) (finding that the Due Process Clause

(footnote continued)

Anglo-American legal tradition pre-dates our own decisions by at least two hundred years.[10] The legal tradition traces its ultimate roots at least to the early thirteenth century: under the 39th Article of the Magna Carta, a citizen could not be deprived of the right of personal security "except by the legal judgment of his peers or by the law of the land." Perry & Cooper, *Sources of Our Liberties*, 17 (1959).

The right to be free of pain likewise finds its source in both legal precedent and important traditions of this Nation. Outside of the legal context, this right is embedded in the professional and ethical standards of physicians and other

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protects an interest in life as well as an interest in refusing life-sustaining medical treatment); *Winston v. Lee*, 470 U.S. 753, 766 (1985) (finding involuntary surgery to remove bullets from defendant's shoulder unreasonable invasion of his body); *Ingraham v. Wright*, 430 U.S. 651, 673-74 (1977) ("The liberty preserved from deprivation without due process include[s] . . . a right to be free from and to obtain judicial relief, for unjustified intrusions on personal security. . . . [This] encompass[es] freedom from bodily restraint and punishment"); *Estelle v. Gamble*, 429 U.S. 97, 103-04 (1976) (stating in the context of prisoners' rights that "denial of medical care may result in pain and suffering which no one suggests would serve any penological purpose. . . . The infliction of such unnecessary suffering is inconsistent with contemporary standards of decency as manifested in modern legislation."); *Rochin v. California*, 342 U.S. 165, 172 (1952) (finding an unconstitutional violation of bodily integrity when police took defendant to hospital and administered an emetic to recover pill swallowed upon arrest); *Schloendorff v. Soc'y of N.Y. Hospital*, 105 N.E. 92, 93 (N.Y. 1914) (stating in a case involving the patient's claim that her doctor had removed a tumor without her consent, that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.").

[10] Blackstone recognized a right to personal security "which consists in a person's legal and uninterrupted enjoyment of his life, his limbs, his body, his health, and his reputation." 1 Blackstone, *Commentaries* *130 (1765). Blackstone extended prosecution to the "preservation of a man's health from such practices as may prejudice or annoy it." *Id.* at *134.

caregivers. Allowing a patient to experience unnecessary pain and suffering of any form is considered substandard medical practice, regardless of the nature of the patient's condition or the goals of medical intervention.[11] Likewise, physicians have a moral and ethical duty to provide relief from pain and suffering.[12] This standard has in fact been recognized since the inception of medical ethics in western

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[11] *See, e.g.*, Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 Wm. Mitchell L.Rev. 1, 4 (2000).

[12] *See, e.g.*, Post et al., *Pain: Ethics, Culture, and Informed Consent to Relief*, 24 J. Law, Med. & Ethics 348 (1996) ("[O]ne caregiver mandate remains as constant and compelling as it was for the earliest shaman – the relief of pain. Even when cure is impossible, the physician's duty of care includes palliation. Moreover, the centrality of this obligation is both unquestioned and universal, transcending time and cultural boundaries."); Wanzer, et al., *The Physician's Responsibility Toward Hopelessly Ill Patients: A Second Look*, 320 New England J. Med. 844 (1989) (concluding that "[t]o allow a patient to experience unbearable pain or suffering is unethical medical practice. . . . The physician should follow these principles without exaggerated concern for legal consequences, doing whatever is necessary to relieve pain and bring comfort, . . . [and t]o withhold any necessary measure of pain relief in a hopelessly ill person out of fear of depressing respiration or of possible legal repercussions is unjustifiable.").

culture,[13] and its underpinnings in contemporary thought derive from many varied and different sources.[14]

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[13] *See, e.g.*, Amundsen, *Medicine, Society, and Faith in the Ancient and Medieval Worlds*, 33 (1996) ("The treatise entitled *The Art* in the Hippocratic Corpus defines medicine as having three roles: doing away with the sufferings of the sick, lessening the violence of their diseases, and refusing to treat those who are overmastered by their diseases, realizing that in such cases medicine is powerless"); Cassell, *The Nature of Suffering and the Goals of Medicine*, 306 New England J. Med. 639 (1982) ("[T]he obligation of physicians to relieve human suffering stretches back into antiquity.").

[14] Members of the American Society of Law, Medicine and Ethics, for example, argue that this standard is based on tenets of professionalism:

> Principled analyses of the doctor-patient relationship suggest that it is the dual obligation of physicians to respect and promote the autonomy of their patients and to protect and enhance their well-being . . . [which includes] relief of pain and suffering. . . . . [W]e submit that providing relief from pain is central to the very notion of healing and, for that reason alone, it requires no exceptions or intellectual artifice for its validity.

Post et al., *supra*, 24 J. Law, Med. & Ethics at 349, 358.

Others, such as the mid-1980s philosopher Rem Edwards, assert that the medical standard is dictated by ethics: "there is a broadly based humanistic ethics which applies to the domain of medical care which gives patients a strong *prima facie* right to freedom from unnecessary pain, . . . [and] there is the duty to do all that can be done within the limits of current medical knowledge and available resources to relieve all the pain and suffering which can be alleviated. . . . [T]hese rights and duties . . . can be derived in one way or another from almost every major philosophical theory of ethics available to us. In that sense they are broadly justified." Edwards, *Pain and the Ethics of Pain Management*, 18 Soc. Sci. Med. 515, 517 (1984) (emphasis added); *accord*, Morris, *The Culture of Pain*, 191 (1991) (observing that "*not* relieving pain brushes dangerously close to the act of willfully inflicting it" (original emphasis)).

(footnote continued)

The decisions of this Court and the arguments of the government itself in other, related contexts are in accord with the standards that inform medical practice. A majority of this Court in *Planned Parenthood v. Casey*, 505 U.S. 833, 852 (1992); *Hudson v. McMillian*, 503 U.S. 1, 9-10 (1992); *Ingraham v. Wright*, 430 U.S. at 673-74, assumed the existence of a fundamental right of a seriously ill patient to be free from unnecessary pain and suffering.

In the United States' *amicus* brief for the petitioners in *Washington v. Glucksberg*, 521 U.S. 702, the Solicitor General cited these decisions to assert that the infliction of severe pain or suffering on an individual implicates a fundamental liberty interest:

> A competent, terminally ill adult has a constitutionally cognizable liberty interest in avoiding the kind of suffering experienced by the plaintiffs in this case. That liberty interest encompasses an interest in avoiding not only severe physical pain, but also the despair and distress that comes from physical deterioration and the inability to control basic

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In fact, the duty of physicians to help patients to be free from pain ultimately implicates the Judeo-Christian religious tradition and encompasses recognition of the role that narcotics may play in achieving this end. For example, at a convention of Catholic physicians in 1957, the Pope responded to a series of questions directed at an individual's right to be free of pain and acknowledged the role of narcotics in safeguarding this right. The Pope stated that "[t]he patient desiring to avoid or relieve pain can in good conscience use those means discovered by science which, in themselves, are not immoral" (Russell, *Freedom to Die: Moral and Legal Aspects of Euthanasia,* 129 (Human Sci. Press 1977) (1975)) and announced that "if . . . the administration of narcotics, itself lead [sic] to two distinct effects, one the relief of pain and the other the shortening of life, it is lawful." *Euthanasia: Recent Declarations of Popes and Bishops*, Life Ethics Centre, Christian Pamphlet No. 3, 8-9 (Alphonse de Valk, C.S.B., ed. 1983).

> bodily or mental functions in the terminal stage of an illness.

Brief for the United States as *Amici Curiae* Supporting Petitioners, *available in* 1996 WL 663185, at *8, 12-13 (1996), in *Washington v. Glucksberg*, 521 U.S. 702 (1997) (No. 96-110).[15]

The right to be free from severe pain and suffering is thus a fundamental liberty interest that is central to the Nation's history and traditions.[16] For these reasons, the government cannot, consistent with the Due Process Clause, abridge the rights of seriously ill patients by preventing or deterring their physicians from recommending controlled substances in kind and quantity sufficient to relieve their pain.[17]

B. The sanctity of the physician-patient relationship.

The right to consult with one's doctor about one's medical condition also is recognized as a fundamental right deeply rooted in our history and legal tradition. The right asserted by the Members—to prevent governmental

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[15] In its *amicus* brief, the United States also argued that a state cannot prevent a person in extreme pain from obtaining medication demonstrated to be safe and effective in relieving that pain (*see id.* 1996 WL 663185 at *13) and listed loss of appetite and nausea as conditions of a terminally ill person that would trigger this liberty interest. *See id.* at *15-16. Solicitor General Dellinger reiterated the existence of this fundamental liberty interest in oral argument. Transcript of Oral Argument, *Washington v. Glucksberg*, 521 U.S. 702 (No. 96-110), *available in* 1997 WL 13671, at *18, *20-21 (Jan. 8, 1997).

[16] *Cf. Vacco v. Quill*, 521 U.S. 793, 807 n.11 (1997) (stating that "[j]ust as a State may prohibit assisting suicide while permitting patients to refuse unwanted lifesaving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended 'double effect' of hastening the patient's death").

[17] *See also* Tucker, *The Death with Dignity Movement: Protecting Rights and Expanding Options After Glucksberg and Quill*, 82 Minn. L. Rev. 923, 936 (1998).

interference with their ability to act on their doctors' treatment recommendations—is based in significant part on imperatives established by the doctor-patient relationship. For this reason as well, the Members' claimed right must be accorded constitutional status.

The Court has acknowledged the sanctity of the physician-patient relationship in numerous substantive due process cases. It was first noted in *Griswold v. Connecticut,* 381 U.S. 479 (1965). There, doctors from Planned Parenthood violated a Connecticut law making it a crime to distribute contraceptives. *Id.* at 480. In finding that the criminalization of contraception violated a right guaranteed by due process, the Court relied on the fact that "[t]his law operates directly on an intimate relation of husband and wife and their physician's role in one aspect of that relation." *Id.* at 482.

The importance of the physician-patient relationship also has been stressed in the abortion cases. For example, in *Roe v. Wade,* 410 U.S. 113 (1973), the Court emphasized that myriad and fundamental privacy and personal liberty interests, such as medical, physical, social, and spiritual choice, were impugned by the criminalization of abortion. *Id* at 153. The *Roe* decision also stressed that such a violation of privacy interests, although personal to the woman, detrimentally affected the physician-patient relationship. *Id.* at 153, 156.[18]

More recently, in *Washington v. Glucksberg*, the Court observed that the State also has an interest in protecting the

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[18] The abortion cases also note the importance of medical consultation to the exercise of fundamental rights. *See Roe,* 410 U.S. at 164; *Casey,* 505 U.S. at 879, 883-84; *Stenberg v. Carhart,* 530 U.S. 914, ___, 120 S.Ct. 2597, 2618 (2000) (O'Connor J., concurring) (stating that, "As we held in *Casey*, . . . any such regulation or proscription [of abortion] must contain an exception for instances 'where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother.'").

integrity and ethics of the medical profession. 521 U.S. at 731. The Court found that, in this regard, "physician-assisted suicide could, it is argued, undermine the trust that is essential to the doctor-patient relationship by blurring the time-honored line between healing and harming." *Id.*

Likewise, in his concurrence in *Washington v. Glucksberg*, Justice Souter relied upon the view that medical assistance may fall within the penumbra of a cognizable liberty interest: "[w]ithout physician assistance in abortion, the woman's right would have too often amounted to nothing more than a right to self-mutilation." 521 U.S. at 778. Justice Souter also affirmed the strong tradition of comprehensive medical care in our society:

> [T]he Court recognized that the good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more that treat symptoms, one who ministers to the patient.

Id. at 779.[19]

The importance of the physician-patient relationship is further demonstrated by the existence of state legislation granting a statutory physician-patient privilege. Currently, forty-one states recognize some form of a physician-patient

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[19] In his concurrence in *Washington v. Glucksberg*, 521 U.S. 702, Justice Stevens also emphasized the intimate nature of the doctor-patient relationship:

> For doctors who have longstanding relationships with their patients, who have given their patients advice on alternative treatments, who are attentive to their patient's individual needs, and who are knowledgeable about pain symptom management and palliative care options, [] heeding a patient's desire to assist in her suicide would not serve to harm the physician-patient relationship.

Id. at 748.

testimonial privilege. *See* Appendix A. Moreover, many of the statutory privileges are very old. New York was the first state to pass a physician-patient testimonial privilege in 1828, with Missouri following suit in 1835. *See* 8 Wigmore on Evidence, § 2380 (rev. ed. 1961). Though physician-patient communication is "subject to reasonable licensing and regulation by the State" (*Casey,* 505 U.S. at 884), when such regulation defeats the purpose of the physician-patient relationship by preventing the physician from fulfilling his or her duties, such regulation is impermissible. *See, e.g., Conant v. McCaffrey,* 172 F.R.D. 681, 694-95 (N.D. Cal. 1997) (holding that government's statutory authority to regulate distribution and possession of drugs did not allow government to quash protected speech between physician and patient).

In this case, the interests arising within the physician-patient relationships are of the highest order. Recognition of the medical necessity defense to prevent governmental interdiction of the Members' personal, self-funded decisions to use medicinal cannabis as recommended by their doctors will safeguard the physician-patient relationships. Moreover, unless unfettered communication and the freedom to act on one's physician's advice are guaranteed by the Due Process Clause in this context, the related fundamental rights of bodily integrity and freedom from pain and suffering will be rendered nugatory.

II. The Members' Fundamental Right Is Different From The Rights Asserted In *Carnohan* And *Rutherford*, Which Therefore Have No Application Here.

The government argues that the right the Members assert here cannot exist because courts have held that there is no fundamental right to use an unapproved drug for medical treatment. *See* Brf. at 25, fn.14 (*citing Carnohan v. United States*, 616 F.2d at 1122; *Rutherford v. United States*, 616 F.2d at 457; and other cases). The government's argument is incorrect.

The cases invoked by the government have no application here. None involved the fundamental right articulated by the Members. Moreover, in all of them, it was the proponents of the asserted constitutional rights, not the government, who sought affirmative, coercive relief. The decision in *Rutherford* in fact confirms that the right to decide whether or not to have effective medical treatment at all is in fact fundamental. *Id.*

In *Carnohan*, for example, the plaintiff brought a declaratory action "to secure the right to obtain and use laetrile in a nutritional program for the prevention of cancer." 616 F.2d at 1121. The relief sought (a declaration that laetrile was not a "new drug" within the meaning of the Federal Food, Drug and Cosmetic Act) fell squarely within the rule-making authority of the Food and Drug Administration (the "FDA"). *Id.* Specifically, the claim in *Carnohan* was that the "state and federal regulatory schemes that require [filing a new drug application] are so burdensome when applied to private individuals as to infringe upon constitutional rights." *Id.* at 1122.

The court of appeals rejected this claim, finding that the plaintiff was required to exhaust his administrative remedies to seek reclassification of the drug laetrile by filing a new drug application with the FDA. *Id.* The appellate court, however, expressly declined to consider whether the plaintiff had "a constitutional right to treat himself with home remedies of his own confection." *Id.*

Unlike *Carnohan*, the Members here do not seek reclassification of any drug or seek to compel the government affirmatively to give them access to any medication. The Members simply assert the right to be free of governmental interference with their obtaining and using, upon their personal physicians' recommendations in accordance with California's Compassionate Use Act, the only medication that has been demonstrated to be effective in alleviating their pain and suffering. These key facts are absent in *Carnohan*.

The government also relies on *Rutherford v. United States*, 616 F.2d 455, another laetrile case. *Rutherford* held that "*the decision by the patient whether to have a treatment or not is a protected right* but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health." *Id.* at 457 (emphasis added). There is no indication that the plaintiffs in *Rutherford* attempted to establish that the drug at issue represented the *only* effective treatment for them. Instead, they simply sought to have a particular *type* of treatment declared to be a fundamental right.

This is a critical distinction. Here, the Members and their doctors have declared that cannabis is the *only* effective treatment for them. Hence, to permit the government to interfere with the Members' use of cannabis is to deny them the right recognized by *Rutherford*: the right to decide whether or not to have medical treatment. Because cannabis is the *only* effective treatment for the Members, to deny them the right to use cannabis is to deny them any medical treatment at all. Cannabis is not simply the "medication of choice," it is the only medication for the Members.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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February 2001

APPENDIX

APPENDIX A

United States Jurisdictions With a Statutory Physician-Patient Testimonial Privilege

State	Code #
Alaska	Alaska R. Evid. 504
Arizona	Ariz. Rev. Stat. § 12-2235
Arkansas	Ark. R. Evid. 503
California	Cal. Evid. Code §§ 990-1007
Colorado	Col. Rev. Stat. § 13-90-107
Delaware	Del. R. Evid. 503
District of Columbia	D.C. Code Ann. § 14 –307
Hawaii	Haw. Rev. Stat. § 504
Idaho	Idaho Code § 9-203
Illinois	735 Ill. Comp. Stat. 5/8-802
Indiana	Ind. Code § 34-46-3-1
Iowa	Iowa Code § 622.10
Kansas	Kan. Stat. Ann. § 60-427
Louisiana	La. Code. Evid. Art. 510
Maine	Me. R. Rev. 503
Michigan	Mich. Stat. Ann. § 600.2157
Minnesota	Minn. Stat. § 595.02
Mississippi	Miss. Code Ann. § 13-1-21
Missouri	Mo. Rev. Stat. § 491.060
Montana	Mont. Code. Ann. § 26-1-805
Nebraska	Neb. Rev. Stat. § 27-504

State	Code #
Nevada	Nev. Rev. Stat. Ann. § 49.225
New Hampshire	N.H. Rev. Stat. Ann. § 329:26
New Jersey	N.J. Stat. Ann. § 2A:84A-22.2
New Mexico	N.M. R. Evid. 11-504
New York	N.Y. Civ. Prac. L. & R. § 4504
North Carolina	N.C. Gen. Stat. § 8-53
North Dakota	N.D. R. Evid. 503
Ohio	Ohio Rev. Code. § 2317.02
Oklahoma	Okla Stat. § 2503
Oregon	Or. Rev. Stat. § 40.235
Pennsylvania	42 Pa. Code § 5929
Rhode Island	R.I. Gen. Laws §5-37.3-6.1
South Dakota	S.D. Codified Laws § 19-13-7
Texas	Tex. R. Evid. 509
Utah	Utah R. Evid. 506
Vermont	Vt. Stat. Ann. §1612
Virginia	Va. Code Ann. § 8.01-399
Washington	Wash. Rev. Code § 5.60.060
Wisconsin	Wis. Stat. § 905.04
Wyoming	Wyo. Stat. Ann. § 1-12-101

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(13)

Supreme Court, U.S.
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No. 00-151

In The

Supreme Court of the United States

UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

~~MOTION FOR LEAVE TO FILE~~ *AMICI CURIAE* BRIEF AND BRIEF OF CALIFORNIA MEDICAL ASSOCIATION AND NATIONAL PAIN FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

May a federal court consider the needs of seriously ill patients when formulating relief in response to a request for an injunction, unless clearly denied that authority by federal statutory law?

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF OF CALIFORNIA MEDICAL ASSOCIATION AND NATIONAL PAIN FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

The California Medical Association and the National Pain Foundation hereby respectfully move for leave to file the attached brief as *amici curiae* in support of Respondents in this case. The consent of the attorneys for the petitioner and respondent has been obtained. The letters of consent have been filed separately with the court in this case.

The California Medical Association ("CMA") is a non-profit, incorporated professional association of more than 30,000 physicians practicing in the State of California. CMA's membership includes California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA and its members share the objective of promoting high quality, cost-effective health care for the people of California.

The National Pain Foundation ("NPF") is a nonprofit educational organization created to address the issue of chronic pain management. The NPF is establishing an extensive network of information regarding proven, integrated approaches to pain management that will draw from traditional, alternative and behavioral approaches to pain management. The Mission of The National Pain Foundation is to create a highly accessible information network that will empower individuals to make optimum use of available resources to manage chronic pain. The

NPF is committed to being an impartial resource for the pain medicine community to promote functional recovery for pain patients.

CMA and NFP move for leave to file this brief in support of Respondents. As is more fully explained in the brief itself, CMA and NFP believe that the ruling of the United States Court of Appeals on medical necessity in this case raises an issue of great importance to the medical community. CMA and NFP have a strong interest in ensuring that patients, with the advice and approval of their physicians, are able to seek and obtain appropriate and effective medical care. CMA and NFP wish to stress that they fully support the appropriate regulation of the safety and efficacy of new drugs by the Food, Drug, and Cosmetic Act and the appropriate control of drugs potentially subject to abuse by the Controlled Substances Act. *Amici* would not support any judicial determination that created a wholesale undermining of those Acts. However, by enacting these general laws to protect public health and safety, Congress cannot have intended to prevent the courts from recognizing and accommodating the desperate need of individual patients. The Court of Appeal's ruling in this case strikes a sound balance between the basic integrity of the federal statutory scheme and the compassionate wisdom of the common law. CMA and NFP believe that physicians and their patients must be free to explore all possible avenues of medical treatment when standard therapies have failed, and no governmental body should impede or punish that effort.

CMA and NFP have reviewed the briefs filed by the parties in this matter and is familiar with the questions involved and the scope of their presentation. CMA and

NFP believe there is a need for additional argument on the issues raised and CMA and NFP are well-placed to provide the Court with the particular perspective of the medical community concerning the impact of the medical necessity defense on the provision of good patient care.

For the foregoing reasons, CMA and NFP respectfully move this Court for leave to file the accompanying brief as *amici curiae* in support of Respondents.

DATE: Feb. 16, 2001 Respectfully submitted,

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Roche, T., "The Potent Perils of a Miracle Drug," Time Magazine (Jan. 8, 2001) 18

BRIEF OF *AMICI CURIAE*

This brief of *amici curiae*[1] is filed in support of Respondents and is submitted on behalf of the California Medical Association and National Pain Foundation (herein referred to as *"amici"*).

INTEREST OF *AMICI CURIAE*

The California Medical Association (CMA) is a nonprofit, incorporated professional association of more than 30,000 physicians practicing in the State of California. CMA's membership includes California physicians engaged in the private practice of medicine, in all specialties. CMA's primary purposes are " . . . to promote the science and art of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession."

The National Pain Foundation ("NPF") is a nonprofit educational organization created to address the issue of chronic pain management. The NPF is establishing an extensive network of information regarding proven, integrated approaches to pain management that will draw from traditional, alternative and behavioral approaches to pain management. The Mission of The National Pain

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[1] Both parties have consented to the filing of this brief. The letters of consent have been filed with the Clerk of the Court. Counsel for a party did not author this brief in whole or in part. No person or entity, other than the *amici curiae*, its members, or its counsel made a monetary contribution to the preparation and submission of this brief.

Foundation is to create a highly accessible information network that will empower individuals to make optimum use of available resources to manage chronic pain. The NPF is committed to being an impartial resource for the pain medicine community to promote functional recovery for pain patients.

ARGUMENT

A. *Amici* Urge This Court to Uphold the Ruling of the Court of Appeals in This Case.

This case presents a very limited question. It asks only whether a federal court may consider the needs of seriously ill patients when formulating relief in response to a request for an injunction, unless clearly denied that authority by federal statutory law. This issue, while narrow, cuts to the heart of the physician-patient relationship.[2]

Amici believe that the concept of medical necessity, as narrowly defined by the Court of Appeals, is wholly appropriate, and indeed essential, to protect the integrity and effectiveness of the physician-patient relationship.[3] Furthermore, that ruling is squarely supported by a long line of common law decisions. Finally, the Court of Appeals' ruling is entirely consistent with the provisions of the federal Food, Drug & Cosmetic Act and the

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[2] This Court could, in fact, affirm the applicability of the concept of medical necessity in this case without explicitly approving the use of cannabis.

[3] Under the Court of Appeals' ruling, the medical necessity defense applies only to patients: 1) who have serious medical conditions, 2) for whom the use of cannabis is necessary in order to treat or alleviate those conditions or their symptoms; 3) who will suffer imminent harm if they are denied cannabis; and 4) **for whom there are no legal alternative to cannabis for the effective treatment of their medical conditions because they have tried other alternatives and have found that they are ineffective, or that they result in intolerable side effects**. *U.S. v. Oakland Cannabis Buyers' Cooperative*, 190 F.3d 1109, 1114 (9th Cir. 1999).

Controlled Substances Act. Accordingly, *amici* urge this Court to uphold that ruling.

B. The Court of Appeals' Ruling on Medical Necessity Supports the Effectiveness of the Physician-Patient Relationship and Promotes Good Patient Care

A patient and his or her physician often embark together on a difficult and frustrating process of exploration and discovery. When medical problems remain intractable, the patient and physician must be free to explore all therapeutic options, and the physician needs the latitude to offer the patient his or her opinion and advice on any and all potential courses of treatment. Neither the courts, nor any other governmental entity, should punish or otherwise impede a desperate patient, acting with the advice and approval of his or her physician, who 1) seeks to relieve his or her serious suffering by using a treatment that has been shown to be effective in his or her case and 2) has tried all conventional treatments without success. Furthermore, those who attempt to aid the patient in that effort should be similarly free from sanction.

Good medicine does not involve just the application of cold data to "a case." Rather, it requires the application of intuition, sensitivity, and creativity to the circumstances of a specific patient. If the patient has an intractable problem, various measures may be tried and abandoned; consultation may be sought; research may be undertaken. To be sure, standard therapies, if available, will certainly be tried first, but if those fail, sound medical opinion supports the exploration of different

options.[4] Sometimes an option will involve the use of unconventional, unapproved, and, in rare instances, even unlawful substances. But the substance may offer the only hope of effective treatment for a particular patient. The law must be flexible enough to permit patients and physicians to discover the option that relieves the suffering of otherwise "untreatable" patients.

The fact that a substance or therapy has not been proven to be effective, by controlled clinical trials, for a particular condition should not invariably preclude its use by a patient. Controlled clinical trials have contributed greatly to scientific knowledge, but they are not the only means of obtaining useful information about a potential treatment modality. "Anecdotal" cases, particularly if they are meaningful in number, may offer critically important guidance to physicians and patients. It is well accepted that patients may take, on prescription, an approved medication for an unapproved medical use, i.e., "off-label" prescription.[5] To deny physicians and their

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[4] It is incontrovertible that some patients with serious medical conditions **cannot be helped by standard therapies**. For example, in a recent report on medicinal marijuana, the prestigious Institute of Medicine noted that, despite new advances in antiemetic (anti-vomiting) medications, 20-30% of cancer patients who receive highly emetogenic chemotherapy will still experience acute emesis. Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* (1999) at p. 151. Others will suffer from conditions for which there is no standard therapy or for whom the side effects of such therapy are intolerable.

[5] The AMA takes the position that "a physician may lawfully use an FDA approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion." Policy 120.988, AMA

patients rights like this would seriously eviscerate the practice of medicine.[6]

In some cases, the only alternative may involve a drug that has been approved for marketing in other countries, but has not yet received approval by the Food and Drug Administration (FDA) in the U.S. For example, there are patients who suffer from debilitating seizures who can obtain relief only from drugs available in Europe, but not the U.S. In other cases, patients may seek relief from various types of alternative therapies, such as herbs, vitamins,[7] meditation, yoga, acupuncture, etc.

Policy Compendium 1996. The AMA Council on Scientific Affairs has reviewed the issue of off-label prescription. The Council stated that the prevalence and clinical importance of unapproved indications are substantial, especially in the areas of oncology, rare diseases, and pediatrics. Report of the Council on Scientific Affairs 3-A-97, "Unlabeled Indications of Food and Drug Administration-Approved Drugs." The California Attorney General has opined that the state and federal drug approval laws were intended to protect consumers from drug manufacturers, not to interfere with the physician's judgment regarding individual patient treatment. *See* 61 Ops.Cal. Atty.Gen. 192 (1978).

[6] Many medications, particularly pain medications, are used for "off-label," or unapproved, purposes. Such off-label use may not be supported by data from controlled clinical trials; nevertheless, it is fully within the ethical practice of medicine. Indeed, it may provide the best – or sole – source of relief for a suffering patient. Despite this fact, many carriers, including the Health Care Financing Administration, unjustifiably refuse to extend coverage to such treatments.

[7] Herbs, vitamins, minerals, botanicals, and similar substances are regulated as "dietary supplements," rather than "new drugs," by the FDA, so long as they are not accompanied by claims of specific medical or health benefits. The Dietary

Physicians may assist patients in identifying whether any of such therapies are likely to be helpful. These therapies may not have been shown to be effective through controlled clinical trials. Yet they may provide a patient's sole source of relief.

The "medical necessity" defense fits well into this patient-physician dynamic. As applied by the Court of Appeals, it represents, not a wholesale judicial nullification of a federal statutory scheme, but an appropriately narrow recognition that individual patients (with their physicians' advice) will sometimes seek unusual or even unlawful remedies when nothing else will alleviate their suffering. Congress would surely not have presumed to overrule, with the broad brush of the federal CSA, such a basic aspect of medicine.

Amici wish to stress that they fully support the appropriate regulation of the safety and efficacy of new drugs by the Food, Drug, and Cosmetic Act (FDCA) and the appropriate control by the CSA of drugs potentially subject to abuse. *Amici* would not support any judicial determination that created a wholesale undermining of those Acts. However, by enacting these general laws to protect public health and safety, Congress did not intend to prevent the courts from recognizing and accommodating the desperate need of individual patients. The Court of Appeals' ruling in this case strikes a sound balance between the basic integrity of the federal statutory scheme and the compassionate wisdom of the common law.

Supplement Health and Education Act (DSHEA), 21 U.S.C. §343(r)(6). Therefore, they have not been rigorously tested for safety and efficacy by controlled clinical trials.

C. The Court of Appeals' Ruling on Medical Necessity Does Not Subvert or Contravene the Food, Drug & Cosmetic Act (FDCA) Nor the Controlled Substances Act (CSA).

1. The Stringent Statutory Criteria for Placement of a Substance in Schedule I of the CSA Are Qualitatively Different From the Criteria That Establish Medical Necessity.

The federal government contends that the Court of Appeals' ruling on medical necessity is inconsistent with the CSA and re-balances the factors already weighed by Congress when it placed marijuana in Schedule I of that Act. However, the concept of medical necessity, as set forth by the Court of Appeals, can quite logically coexist with that congressional determination.

By placing a substance in Schedule I, Congress has **not** thereby decided that the substance can provide **no** medical benefit to **any** individual under **any** circumstances. The following factors determine a substance's categorization as Schedule I:

(A) The drug or other substance has a high potential for abuse;

(B) The drug or other substance has no currently accepted medical use in treatment in the United States;

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

The finding that a substance lacks "currently accepted medical use" within the meaning of the **statutory term** does not suggest that there is **no** evidence of

the substance's medical effectiveness, and, indeed, **the federal government has never before made such a claim.** The requirements for a finding of "currently accepted medical use" are both stringent and complex. In a proceeding seeking to move a substance from Schedule I to Schedule II, the Drug Enforcement Administration (DEA) has stated that it will examine the following factors in determining whether the drug has a "currently accepted medical use:"

1. The drug's chemistry must be known and reproducible;

2. There must be adequate safety studies;

3. There must be adequate and well-controlled studies proving efficacy;

4. The drug must be accepted by qualified experts; and

5. The scientific evidence must be widely available.

See Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994).[8]

During litigation involving a petition to reschedule marijuana, the DEA explained the meaning of each of these factors. *See* 57 Fed.Reg. 10499, 10506 (March 26, 1992). According to the DEA, a failure to meet **any** of the factors precludes a drug from having a "currently accepted medical use." 57 Fed.Reg. 10507.

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[8] These factors were created by the Final Order of the DEA Administrator in the course of rescheduling litigation, *see* 57 Fed.Reg. 10499 (March 26, 1992) and subsequently approved by the Court of Appeals.

a. Known and Reproducible Chemistry

To satisfy this criterion, the substance's chemistry must be scientifically established to permit it to be reproduced into dosages which can be standardized. The listing of the substance in a current edition of one of the official compendia, as defined by the Food, Drug & Cosmetic Act, 21 U.S.C. §321(j), is sufficient generally to meet this requirement.

b. Adequate Safety Studies

To satisfy this criterion, there must be adequate pharmacological and toxicological studies, done by all methods reasonably applicable, on the basis of which it could fairly and responsibly be concluded, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that the substance is safe for treating a specific, recognized disorder.

c. Adequate and Well-Controlled Studies Proving Efficacy

Under this criterion, there must be adequate, well-controlled, well-designed, well-conducted, and well-documented studies, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of which it could fairly and reasonably be concluded by such experts, that the substance will have its intended effect in treating a specific, recognized disorder.

d. Drug Accepted by Qualified Experts

Under this requirement, the drug must have a New Drug Application (NDA) approved by the FDA, or a consensus of the national community of experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, must accept the safety and effectiveness of the substance of use in treating a specific, recognized disorder. A "material" conflict of opinion among experts precludes a finding of "consensus."

e. Scientific Evidence Must Be Widely Available

This element requires that, in the absence of NDA approval, information concerning the chemistry, pharmacology, toxicology, and effectiveness of the substance must be reported, published, or otherwise widely available in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, to fairly and responsibly conclude the substance is safe and effective for use in treating a specific, recognized disorder. 57 Fed.Reg. at 10506.

The DEA Administrator has made it clear that, in determining whether the above five standards have been met, the DEA will **not** consider as proof either "isolated case reports" or the "clinical impressions of

practitioners."[9] 57 Fed.Reg. at 10506-07. In other words, in refusing to remove marijuana from Schedule I, the DEA Administrator did not reject evidence that in individual instances, marijuana may have provided great benefit, but rather ruled that such "anecdotal cases" could not satisfy the **demanding statutory criterion** of "currently accepted medical use."

The Court of Appeals' ruling on medical necessity therefore does not set aside the congressional judgment concerning placement of a substance in Schedule I. Instead, ~~its~~ ruling recognizes that the CSA humanely leaves room for the reality of "anecdotal cases," i.e.,

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[9] The Administrator also will not consider:

- Opinions of person not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue;
- Studies or reports so lacking in detail as to preclude responsible scientific evaluation;
- Studies or reports involving drug substances other than the precise substance at issue;
- Studies or reports involving the substance at issue combined with other drug substances;
- Studies conducted by persons not qualified by scientific training and experience to evaluate the safety and effectiveness of the substance at issue;
- Opinions of experts based entirely on unrevealed or unspecified information; or
- Opinion of experts based entirely on theoretical evaluations of safety or effectiveness.

Id.

individual patients who, in consultation with their physicians, have discovered relief from their tormenting medical condition only by using a particular substance.

2. When Enacting the CSA, Congress Demonstrated a Concern for the Public Interest That is Perfectly Consistent With the Concept of Medical Necessity.

The federal government asserts that the CSA contains an "absolute ban" on the distribution of cannabis and other Schedule I substances outside the "strict confines" of the CSA. Brief for the Petitioner at p. 29. However, the clear statutory language of the CSA demonstrates that Congress anticipated instances in which the public interest would require a relaxation of such "confines." There is no indication that Congress intended to limit the equitable power of a district court to fashion appropriate injunctive relief, including relief that incorporates the concept of medical necessity, when it is asked to enforce the Act's provisions. Indeed, rather than undermining the administration and effectiveness of the CSA, the concept of medical necessity is perfectly consistent with the structure of that Act.

When it enacted the CSA, Congress repeatedly recognized that the stringent requirements and prohibitions of the Act must often be tempered by a compassionate consideration of the public interest. Furthermore, contrary to the federal government's contention, when considering this public interest, Congress explicitly contemplated that a controlled substance, including one on Schedule I, ***may*** under some circumstances be manufactured, distributed,

or dispensed outside of a research program approved by the FDA and conducted by a practitioner registered with the DEA. For example, the CSA generally states that anyone who manufactures, distributes, or dispenses a controlled substance must obtain a registration from the Attorney General (delegated to the DEA). 21 U.S.C. §822(a), (b). However, **this requirement may be completely waived for a manufacturer, distributor, or dispenser if such a waiver is consistent with the public health and safety. 21 U.S.C. §822(d).**

Furthermore, Congress has deliberately **constrained** the DEA's power to **refuse** to register a manufacturer or distributor. The DEA **must** register an applicant to distribute a Schedule I or II substance **unless** it determines that the issuance of such registration is **inconsistent with the public interest**.[10] 21 U.S.C. §823(b). Similarly, the DEA **must** register an applicant to manufacture a Schedule I or II substance if it determines that such registration is consistent with the public interest and with U.S. international obligations.[11]

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[10] In determining the public interest, the DEA must consider, among other things, whether there will be effective control against diversion of the substance into other than legitimate medical, scientific, and industrial channels. 21 U.S.C. §823(b)(1). This clear distinction between legitimate "medical" and "scientific" suggests that there can be lawful medical uses of a Schedule I substance outside of a research ("scientific") program.

[11] When imposing these limits on the DEA's discretion, Congress made no distinction in the type of controlled substance at issue. That is, the standards for issuance of a registration are consistent, even if the controlled substance at issue falls within Schedules III, IV or V. *See* 21 U.S.C. §§823(d),

By enacting such provisions, Congress deliberately built a substantial degree of flexibility into the CSA, in order to take into account the needs of a specific situation.[12] Congress has already contemplated that the many

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(e). The only difference is that, under a registration granted for a Schedule I or II substance, a registrant cannot manufacture or distribute a Schedule I or II substance other than those specified in the registration, nor manufacture any quantity in excess of its assigned quota. 21 U.S.C. §823(c). Thus, under the CSA, Schedule I is not a *sui generis* category, subject to unique and inflexible requirements. Indeed, the standards for issuance of a registration for distribution and/or manufacture are absolutely the same for a Schedule I and a Schedule II substance, even though Schedule II substances can be prescribed by physicians and dispensed by pharmacies.

[12] Canada allows patients to obtain access to unapproved/controlled substances, **including cannabis**, through Canada's "Section 56 exemption" to its controlled substances act. Under section 56, the Minister of Health has the discretionary power to grant exemptions from all of any of the provisions of the act or its regulations in exceptional circumstances. Section 56 states that the Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons from the application of all or any of the provisions of the CDSA if, in the Minister's opinion, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest. *See* also, Health Canada, Interim Guidance Document, Exemption Under Section 56 For Medical Purposes, *http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/cds/guides/interim___e.html.*

This is precisely what is permitted under our CSA. As indicated above, the CSA is replete with references to the Administrator's right to waive the provisions of the CSA if that would serve the public interest or otherwise be appropriate. Congress thus intended that the CSA would be sufficiently flexible and capacious to be able to tolerate such exceptions to its provisions. Surely, in light of this flexibility, it cannot be

requirements and prohibitions can be modified on a case-by-case basis. There is, therefore, no reason to conclude that Congress intended to deprive the federal courts of a similar power, particularly when that power is so well-established in the common law.[13]

That the CSA should have such flexibility is not surprising. The CSA, like the FDCA, is largely directed toward the regulation of commercial, and the prohibition

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concluded, merely from the CSA's structure and penumbras, that Congress intended to prohibit a federal court also from recognizing the public interest when it is asked to apply that law.

[13] This Court should consider the laws of sister sovereigns when determining the compatibility of the common law concept of medical necessity with the FDCA and CSA. For example, Canada has a regulatory system that parallels our own. It has statutory schemes and regulatory bodies that protect the public from ineffective and unsafe medicines (The Food and Drug Act and Regulations) and control the manufacture and distribution of drugs that may be subject to abuse (the Controlled Drugs and Substances Act (CDSA)). However, even if a drug has not been approved for any medical condition, and even if it is a controlled substance, patients in Canada, with the approval of their physicians, can obtain access to it for medical treatment through Canada's Special Access Programme (SAP).

The SAP has a mandate to provide access to non-marketed drugs to practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, are unavailable, or offer limited options. It provides the authority for a manufacturer to sell a specific quantity of a drug and therefore to grant access to a drug which cannot be otherwise sold or distributed in Canada. Health Canada, Special Access Programme, *http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/edrg.html*. Such an exemption procedure has not eviscerated the effectiveness of Canada's regulatory scheme.

of "black market," manufacturing and distributing/dealing. Under its primary offense provision, it is unlawful for a person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance. The penalties for a violation of this provision are substantial, but the quantities of controlled substances required to trigger such penalties are also substantial. *See* 21 U.S.C. §841 (Prohibited Acts A).

By contrast, the offense and penalty provisions that relate to individual use and possession are far less severe. 21 U.S.C. §§844, 844a. Indeed, the possession of a controlled substance in a personal use amount is subject only to civil penalty, which can be compromised, modified or entirely remitted by the DEA. 21 U.S.C. §844a(a), (f). Such a penalty can be assessed only after the individual has been given an opportunity for a hearing. Section 844a(e). If, after such a hearing, the Attorney General issues a penalty order, the individual may challenge that order in federal court. The facts of the violation must be proved beyond a reasonable doubt. Section 844a(g). Thus, the recognition of a common law defense such as the defense of necessity, that protects individual personal use in very special circumstances, is not inconsistent with the predominant purpose of the CSA and, indeed, would seem to be invited by provisions such as these.[14]

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[14] At the very least, we urge the Court to recognize that the defense can be raised by **an individual patient** who meets the criteria established by the Court of Appeals and who seeks to **possess and use cannabis on the advice of his or her physician**.

3. Allowing Patients to Raise the Medical Necessity Defense Will Not Impede The Government's Ability to Enforce the CSA.

The medical necessity defense will not interfere with the government's ability to enforce the CSA. In their enforcement activities, the DEA and the Department of Justice must regularly determine, on a case-by-case basis, whether a situation involves legitimate medical use or unlawful recreational/street use. Many street drugs, such as cocaine and methamphetamine, have lawful medical applications.[15] Furthermore, approved Schedule II products, such as methadone or oxycontin, are not uncommonly diverted to non-medical uses.[16] Indeed, if a substance is listed in **either** Schedule I or Schedule II (the latter being available for general prescription by physicians), it is deemed to have a "high potential for abuse." 21 U.S.C. §812. A potentially addictive substance remains in Schedule I only if it has not been approved for any medical indication by the FDA. R. Cooper, "Therapeutic Use of Marijuana and Heroin: The Legal Framework," 35 *Food Drug Cosmetic Law Journal* 68 (1980); IOM Report at p. 210 n.++. Once the FDA approves a substance for at least one medical indication in at least one patient population, the Drug Enforcement Administration (DEA) does not have the power to retain the substance's placement in Schedule I.

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[15] Cocaine and methamphetamine are among the substances listed in Schedule II. 21 U.S.C. §812.

[16] *See* T. Roche, "The Potent Perils of a Miracle Drug," Time Magazine (Jan. 8, 2001).

Therefore, if the FDA were to approve another Schedule I substance, such as 3,4-methylenedioxymethamphetamine (MDMA or "ecstasy"),[17] for some medical indication, physicians would be allowed to prescribe it (including perhaps off-label) for a variety of indications, and the DEA would be forced to distinguish between legitimate and illegitimate uses. As with cocaine, methamphetamine, and other drugs, the facts and circumstances surrounding the case, including the existence and validity of a physician's written approval or prescription, will establish the nature of the person's use. The DEA commonly deals with this issue, and the CSA has not thereby been subverted or eviscerated.[18]

The above discussion amply demonstrates that the government's reliance on the "closed" structure of the CSA does not support its contention that the Act inherently precludes a court from applying the concept of medical necessity.

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[17] A Phase 1 safety study was approved by the FDA in 1992 and completed in 1995 by Dr. Charles Grob at Harbor-UCLA Medical Center. *See* C. Grob et al., "Psychobiologic Effects of 3,4-methylenedioxymethamphetamine (MDMA) in Humans: Methodological Considerations and Preliminary Observations," 73 *Behav. Brain Res.* 103 (1996).

[18] To be sure, the FDA has not yet approved cannabis for a particular medical condition. However, the government's arguments do not apply only to cannabis; they would encompass **any** unapproved drug or medicine, whether or not that substance is listed in Schedule I.

4. The Food, Drug & Cosmetic Act (FDCA) Does Not Displace the Concept of Medical Necessity.

The federal government contends that the FDCA has "rejected reliance on the subjective views of individual physicians and patients" to support the use of a new medicine. However, the FDCA was enacted primarily to regulate **commercial transactions** involving medical drugs, as well as food, cosmetics, and medical devices. Its purpose was to protect unwitting consumers from unsafe or ineffective medications. It prohibits, among other things, acts which involve the **interstate** movement of misbranded or adulterated drugs, including those that have not been approved by the FDA for any medical use (and are therefore misbranded). 21 U.S.C. §331(a)-(d).[19]

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[19] Despite the federal government's argument to the contrary, the Court of Appeals' ruling in this case is quite unlike that of the Court of Appeals reviewed in *U.S. v. Rutherford*, 442 U.S. 544 (1979), which involved an improper judicial interference with congressional intent. In *Rutherford*, the Court of Appeals had ruled that the "safety" and "effectiveness" requirements of the federal Food, Drug and Cosmetic Act could have "no reasonable application" to terminally ill patients, thereby creating a wholesale exception to the requirements of the Act for all such persons. The Court of Appeals' ruling does not involve such a broad rewriting of a federal law. Rather, it applies only to a limited number of patients who, **in the face of an enforcement action brought by the federal government,** merely desire to be left alone: to be allowed to obtain and use a medication that has been **shown to the satisfaction of their physician to be the only source of relief for their torments**.

In *Rutherford*, the Supreme Court stressed that the ruling of the Court of Appeals would effectively have "den[ied] the [FDA] Commissioner's authority over all drugs, however toxic

The Act **was never intended to regulate individual consumption of medical drugs, nor does it directly govern the practice of medicine:**

> The FD&CA does not reference the practice of medicine and FDA does not view its mission to include regulation of the practice of medicine. FDA's responsibility is the market introduction of new medical products for particular uses. . . .

Attachment to letter from FDA to Hon. Joseph Barton, Chairman, Subcommittee on Oversight and Investigation, House Committee on Commerce (Apr. 14, 1995). For example, physicians may prescribe, and pharmacists may thereby dispense, drugs "off label," i.e., for "unapproved" or "unlabeled" indications.[20] To be sure, such a

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or ineffectual" for terminal cancer patients. 442 U.S. 557-58, citing *U.S. v. Rutherford*, 582 F.2d 1234, 1236 (10th Cir. 1978). This would clearly have contravened the intent of Congress, which "would reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise." *Id.* By contrast, the concept of medical necessity, as defined by the Court of Appeals, requires a patient to demonstrate that cannabis is necessary to prevent imminent harm. Therefore, the concept incorporates a definitional protection against ineffective "panaceas." Accordingly, the Court of Appeals' limited ruling on medical necessity in this case cannot be compared to the far-reaching judicial fiat that this Court rightly rejected in *Rutherford*.

[20] This is also true of medical devices. In fact, the FDA Modernization Act (FDAMA) explicitly prohibits FDA intrusion into medical practice with regard to the off-label use of devices:

> Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally

drug has received approval from the FDA for some indication. Therefore, the manufacturer has established that the drug is reasonably safe and effective for that indication. However, the fact that the FDA has approved a medication for a particular use does not necessarily mean that the medication is safe for an off-label use or population. An investigational drug is tested within a particular patient population and its benefits and risks are assessed within that population. Its safety profile, and the balance of risks and benefits, may be quite different in another patient group, with different medical problems, different concomitant medications, and different vulnerabilities. Thus, a physician who prescribes a medication off-label often is forced to do so with much more limited information about the safety risks of that medication.

Furthermore, although the FDCA prohibits manufacturers from promoting a drug for an unapproved use,[21] it does not restrict other persons – if they derive no direct commercial interest from the sale or distribution of the product – from making such claims. Indeed, such persons may make claims about a drug or dietary supplement, even if the FDA has never evaluated the drug or dietary supplement for **any** medical indication. The FDA does not question the right of physicians to describe, in a

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marketed device to a patient for any condition or disease within a legitimate health-care-practitioner-patient relationship.

21 U.S.C. §396.

[21] But *see Washington Legal Foundation v. Henney*, No. 99-5304, 2000 WL 122099 (D.C.Cir. Feb. 11, 2000) described in 65 Fed.Reg. 14286 (Mar. 16, 2000) (discussing the extent to which manufacturers may engage in certain promotional activities).

formal educational conference or in a peer-reviewed journal, the case of a patient who obtained benefit from an unapproved use of a drug or from an unapproved drug, and to suggest that the drug may have broader usefulness for that medical condition. As indicated above, the FDA has repeatedly stressed that it does not have jurisdiction over the practice of medicine.

Importantly, the FDCA does not flatly prohibit a physician from prescribing or dispensing an unapproved drug outside of the bounds of an approved investigational drug study. To the contrary, the FDCA explicitly permits a physician, or a pharmacist upon a physician's order, to compound a drug product for an identified patient. Such compounded drug product **is exempt** from the requirements that the FDCA would otherwise impose on a "new drug," i.e., only after FDA approval of an investigational new drug (IND) for a particular research project or of a new drug application (NDA) for commercial marketing. 21 U.S.C. §353a.

In short, such provisions indicate that Congress recognized that there will be instances wherein a particular patient's needs can and must be addressed outside of the confines of the new drug approval process. Therefore, contrary to the federal government's contention, the FDCA has "windows" that are wide enough to accommodate the concept of medical necessity.

D. The Court of Appeals' Ruling Does Not Conflict With the Recent Congressional Declaration Opposing State Medicinal Cannabis Legislation.

The federal government contends that a medical necessity exception to the CSA conflicts with the recent congressional legislation opposing the legalization of medicinal cannabis outside the procedures established by the FDCA. Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761. However, there is nothing in that legislation that reflects a congressional intent to abrogate the well-established common law doctrine of necessity. Similarly, there is no evidence that, in enacting that statement, Congress sought to place narrow limits on a court's equitable power to formulate appropriate injunctive relief in a particular case.

As the federal government correctly states, that declaration was prompted by state initiatives around the country to decriminalize cannabis for medicinal uses. Many of these initiatives have an extremely broad reach and authorize the use of medical marijuana for a wide variety of medical conditions. For example, Proposition 215, the California initiative, authorizes a patient, with the approval or recommendation of his or her physician, to possess and cultivate cannabis for medical use if the patient has any of the following conditions: "cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or ***any other illness for which marijuana provides relief.***" Cal. Health & Safety Code §11362.5(b)(1)(A) (emphasis added).

The scope of such an initiative bears no resemblance to the doctrine of necessity. There is no requirement that the patient has failed on, or even tried, other standard therapies. There is no requirement that the patient's condition be serious or debilitating. There is no requirement that cannabis must be necessary for the effective treatment of that condition. In short, such initiatives do potentially impinge upon federal regulatory concerns.[22] The congressional concern articulated in the declaration targets that situation.

However, by contrast, the medical necessity doctrine is sharply confined. Only those patients who have tried all other standard therapies, who have a serious medical condition, and who will suffer imminent harm if they are not able to use cannabis, will fall within it. The congressional legislation did not address this narrow category of desperate patients, nor did it seek to prevent a court, acting in equity, from considering the plight of such patients when assessing the public interest.

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[22] For this reason, CMA opposed Proposition 215.

E. The Availability of Complex and Prolonged Legislative, Political and Judicial Processes Does Not Offer A Reasonable "Lawful" Alternative Where Seriously Ill and Dying Patients Are Involved.

The federal government further argues that the medical necessity defense has no application when a defendant can seek relief through the political or administrative process. While this contention may hold true for the defense of necessity in certain other contexts, it certainly cannot apply in cases involving patients with an urgent need for medical treatment.

A patient with a life-threatening or otherwise serious medical condition, who has not been able to obtain medical relief from standard therapies, cannot be expected to suffer until the completion of complex, expensive and time-consuming political, legislative, and judicial processes. Any effort to seek the rescheduling of marijuana, even if ultimately successful, would necessitate many years of waiting. In 1972, the National Organization for the Reform of Marijuana Laws (NORML) filed a petition to reschedule marijuana under the CSA. After prolonged litigation and many days of hearings, an administrative law judge recommended that marijuana be rescheduled to Schedule II. In so doing, Judge Francis Young made extensive findings of fact on the issue of marijuana's currently accepted medical use. He found that a "significant minority" of physicians accepted marijuana as medically useful and concluded:

> The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very

> ill people, and doing so with safety under medical supervision.

In The Matter of Marijuana Rescheduling Petition, Docket No. 86-22 (Sept. 6, 1988). However, the DEA Administrator rejected Judge Young's recommendation and findings:

> [T]he effectiveness of marijuana has not been documented in humans with scientifically-designed clinical trials. While many individuals have used marijuana and claim that it is effective in treating their ailments, these testimonials do not rise to the level of scientific evidence.

Marijuana Scheduling Petition, 54 Fed.Reg. 53767, 53784. The Administrator did not deny that a "significant minority" of physicians accepted the medical efficacy of cannabis, nor that patients had benefited from its use; but rather ruled, among other things, that this was not sufficient to meet the "currently accepted medical use" statutory standard. *Id.* at p. 53783-4. The Administrator's findings were upheld in 1994 by a federal Court of Appeals under a "substantial evidence" standard. *See Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C.Cir. 1994). *See also Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936 (D.C.Cir. 1994); *NORML v. DEA*, 559 F.2d 735 (D.C.Cir. 1977); *NORML v. Ingersoll*, 497 F.2d 654 (D.C.Cir. 1977). ***This litigation dragged on for 22 years.***

Based on new scientific evidence, Mr. Jon Gettman filed a cannabis rescheduling petition on July 10, 1995. In 1997, his petition was forwarded by the DEA to the Department of Health and Human Services (HHS) for a scientific and medical review and scheduling recommendation. Brief for the Petitioner at p. 24 n.12. Mr. Gettman is still awaiting a response from HHS. After **almost six**

years, he has still not received even this initial determination, much less a final disposition after the culmination of any ensuing litigation. Surely, desperately sick and dying patients and their physicians should not be required to await the completion of such a prolonged and onerous process. Indeed, the federal government's suggestion that dying patients, and those attempting to assist them, should petition the government to reschedule marijuana ignores the fact that "[T]he law implies a reasonableness requirement in judging whether legal alternatives exist." *U.S. v. Schoon*, 971 F.2d 193, 198 (9th Cir. 1992), cert. denied, 504 U.S. 990 (1992).

Patients will suffer unspeakably and perhaps die before the "legal alternative," i.e., a petition seeking the rescheduling of cannabis, will be finally resolved. Under no stretch of the imagination can such a "legal alternative" be considered reasonable.

CONCLUSION

The Court of Appeals' ruling on medical necessity comports fully with the practice of medicine and good patient care, is well-established in the common law, and is consistent with federal statutory law. Accordingly, for the foregoing reasons, *amici* urge this Court to uphold that ruling.

DATE: February 16, 2001

Respectfully submitted,

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UNITED STATES OF AMERICA,
Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND
JEFFREY JONES,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

Brief *Amici Curiae* of the American Public Health Association, California Nurses' Association, Lymphoma Foundation of American, Irvin Henry Rosenfeld *et al.*, in Support of Respondents
[additional *Amici* listed on inside of front cover]

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I. INTEREST OF THE AMICI*

Amici Curiae are health care and medical organizations – including the American Public Health Association, the world's largest public health organization – whose memberships are comprised of physicians, nurses, public health officers, researchers and care providers, as well as individuals suffering from serious and debilitating illnesses and their families. *Amici* also include four persons who have received herbal cannabis from the federal government for more than a decade to help treat their serious illnesses.[1]

Amici have different experiences, expertise, and perspectives on medical, scientific and public health issues, but are united in their knowledge that there is a small but significant percentage of seriously ill patients who do not respond to or cannot tolerate conventional therapies. For these individuals, the art of medicine – the ability of treatment providers to work closely with a patient to fashion or modify a treatment regimen tailored to the patient's unique needs at a particular moment in time, even in the absence of a clear scientific roadmap – assumes heightened importance.

Amici join together in this brief to underscore the efficacy and legitimacy of cannabis as medicine – a sometimes necessary medicine – and to refute the disingenuous claims to the contrary of the non-medical groups who have weighed in on behalf of the federal government in this case. In supporting the doctrine of

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* No entity or counsel apart from those whose names appear on this Brief have contributed monetarily or substantively to its production. Sup. Ct. R. 37.6.

[1] Descriptions of *Amici Curiae* are set forth in the Appendix to this brief.

medical necessity and providing this Court with a review of recent literature describing the therapeutic properties of cannabis and the plight of patients who derive relief from it, *Amici* do not take a position on whether cannabis should be removed from Schedule I of the Controlled Substances Act. But *Amici* do take issue with the assertions of the government's *Amici* that the medical use of cannabis is simply a stalking horse for marijuana legalization, Br. *Amicus Curiae* of Drug Free America Foundation at 3, 8-9, is part of a "homosexual" agenda, Br. *Amicus Curiae* of Family Research Council at 18, that the therapeutic qualities of herbal cannabis lack scientific grounding, id. at 13-15, or that there are conventional therapies that always work better than cannabis for seriously ill patients, id. at 2. Medical literature and the documented experiences of a diverse body of patients belie these claims.

Each party has given its consent, in writing, to the filing of this Brief.

II. PRELIMINARY STATEMENT

This case raises a very narrow issue. It asks only whether federal courts may consider the plight of suffering patients when exercising equitable powers in response to a request for injunctive relief, when not clearly deprived of that power by a federal statutory scheme.[2] How this narrow

[2] This case does not raise the validity vel non of California's Compassionate Use Act of 1996, Cal. Health & Safety Code § 11362.5, or of similar laws enacted in states that together comprise the majority of the country's populace. Such laws have a far broader scope than the doctrine of medical necessity articulated by the Court of Appeals. The Compassionate Use Act, for example, authorizes a patient to use medicinal cannabis for any medical condition, so long as the patient and his or her physician have determined that cannabis might provide relief. "Medical necessity" patients comprise a small subset of those covered by

question is answered, though, can affect the health and well-being of seriously ill persons for whom cannabis provide the only effective relief. We urge this Court to take its cue from the United States' Institute of Medicine ("IOM") and answer that question in the affirmative.

As Dr. John Benson, Jr., Dean of the Oregon Health Sciences University School of Medicine and principal investigator for the IOM, stated in the release of the IOM Report, MARIJUANA AND MEDICINE, ASSESSING THE SCIENCE BASE (1999) [hereinafter "IOM Report"]:

> [P]hysicians frequently encounter patients who do not respond well to standard medications, or for whom adjunct therapies are needed. For these patients, we found that cannabinoids appear to hold potential for treating pain, chemotherapy-induced nausea and vomiting, and the poor appetite and wasting caused by AIDS or advanced cancer. . . . We do not recommend smoking marijuana for *long-term* medical use . . . [and] see little future in smoked marijuana as a medicine. That said, **we conclude[] that there are some limited circumstances in which we recommend smoking marijuana for medical uses.**

Opening Statement of J. Benson, IOM News Conference March 17, 1999 (emphases added).

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such state laws. This case raises only issues of federal statutory and common law and the power of the federal courts, and could easily have arisen in a state that has yet to decriminalize the medicinal use of cannabis.

This statement is not an isolated opinion, but confirms the conclusions of numerous credentialed clinicians and researchers. *Amici* for Petitioner ignore the findings of the IOM Report that support Respondents, citing instead only those portions of the very balanced Report that point to the potential difficulties of cannabis use. As usual, the truth lies somewhere between the claims of the most extreme anti-cannabis and pro-cannabis advocates. This Court should be guided by the full range of facts, not selective characterizations. On balance, the facts support Respondents.

III. SUMMARY OF ARGUMENT

A small but significant number of seriously ill patients who suffer from cancer, HIV/AIDS, multiple sclerosis, epilepsy, or other conditions do not benefit from, or cannot tolerate, the leading or conventional therapies available in the medical armamentarium. Some of these patients, together with their physicians, have found cannabis to be effective at alleviating symptoms of their condition or side effects of their treatment. The experiences of patients, the observations of their physicians, the conclusions of medical researchers, and the recent findings of blue-ribbon government panels undeniably demonstrate that cannabis has therapeutic properties, which, for some people, can mean the difference between life and death or relative health and severe harm.

What is more, the side effects of cannabis are typically less severe than those caused by conventional medications used to treat debilitating illnesses and conditions. Indeed, first-line therapies for cancer and HIV/AIDS, for example, can induce acute or chronic nausea or anorexia for which cannabis provides the only relief for some patients.

Nor is the prescribable component of cannabis, synthetic THC (Marinol), an adequate alternative for those patients for whom cannabis provides the only relief. Marinol has several shortcomings, including slow uptake, inability to titrate, and difficulty to swallow. In addition, Marinol does not contain CBD, another component of cannabis that, unlike THC, has been shown to be neuroprotective, anti-inflammatory, and anti-convulsant.

Lastly, to the extent the government acknowledges that the constituent components of cannabis, together or in isolation, can provide important therapeutic benefits, it is clear that the medical needs of seriously ill patients for whom cannabis provides the only relief will not have their needs met anytime soon by the federal government or private sector.

Accordingly, the judgement below should be affirmed.

IV. ARGUMENT

A. Abundant Scientific Evidence Demonstrates That Cannabis Has Important Therapeutic Benefits.

As any health care professional can attest, no therapy is effective 100% of the time for all patients. And although almost all ailments can be treated with more than one medication, a small but significant percentage of patients suffering from debilitating or life-threatening illnesses do not benefit from any conventional therapies currently offered by modern medicine. See Declaration of Dr. Marcus Conant,

J.A. at 99. Clear illustrations of this are seen in some people who suffer from acute or chronic pain, nausea, wasting, muscle spasms and seizure disorders.

While Petitioner, and especially the *Amici* for Petitioner, take strong issue with the therapeutic role of herbal cannabis, the scientific literature – and the highly respected research panels from the United States and Great Britain – make clear that there is widespread agreement that cannabis is effective in alleviating the symptoms of many patients who have not obtained relief from conventional treatments.[3]

1. The U.S. Institute of Medicine and the British House of Lords Independently Confirm that Cannabis is Medically Appropriate for Some Patients.

Leading researchers and governmental institutions in the United States and Britain have independently affirmed that herbal cannabis is a crucial medical option for a small class of seriously ill patients who do not benefit from conventional therapies. Specifically, over the last four years, the federal Institute of Medicine[4] and Britain's House of Lords each undertook an extensive scientific review of cannabis and its constituent cannabinoids to assess the

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[3] The term "herbal cannabis" or simply "cannabis" refers to the unrefined plant, in keeping with the terminology of most scientific literature. The term "crude marijuana" used by *Amici* for Petitioner is inaccurate as a scientific term for Cannabis sativa L.

[4] The Institute of Medicine was chartered in 1970 by the National Academy of Sciences (NAS) to bring professionals in different disciplines together to examine policy matters pertaining to the health of the nation. The IOM furthers NAS' responsibility to advise the federal government on such issues pursuant to an 1863 Congressional charter.

medical and public health benefits and risks posed by this plant. Among their key findings, both institutions reached the following conclusions: 1) there are several medical conditions for which a significant minority of patients do not respond to the standard leading therapies; 2) for some of these patients, herbal cannabis provides important relief from life-threatening or seriously debilitating symptoms; and 3) the side effects of herbal cannabis treatment are no worse, and often much less harsh, than those caused by conventional medications and therapies.

a. The Institute of Medicine

In 1997, largely in response to the passage of California's Compassionate Use Act and the subsequent decision of a federal district court to enjoin the federal government from threatening California physicians with sanctions if they discussed the medical benefits of cannabis with their patients, Conant v. McCaffrey, 172 F.R.D. 681 (N.D. Cal. 1997), the White House Office of National Drug Control Policy commissioned the national Institute of Medicine to undertake an extensive review of the scientific evidence of the therapeutic applications of cannabis. The IOM's report, "Marijuana and Medicine: Assessing the Science Base," was published in the spring of 1999.

The IOM assessed a wide array of evidence and testimony. It arrived at six recommendations. Those recommendations primarily emphasize the desirability of further research into the effects of cannabinoids and the development of alternative delivery systems by which patients could ingest cannabis or its constituent elements through methods other than smoking. Critically, however, the IOM Report recognized that there are a number of medical conditions for which currently available therapies

fail to serve a significant minority of patients but for which cannabis has a demonstrated medical benefit.

The IOM's findings regarding the medical efficacy of herbal cannabis to treat acute nausea and vomiting, wasting, and muscle spasticity are discussed in more detail below. But a principal conclusion reached by the IOM – a conclusion that the government's *Amici* omit from their briefs – is that the use of herbal cannabis is medically appropriate for certain patients suffering from debilitating conditions who have unsuccessfully tried all government-approved therapies to treat their conditions, and who are under the care and monitoring of a physician.[5] IOM Report at 179.

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[5] Specifically, the IOM Report suggested that:

> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms . . . must meet the following conditions: Failure of all approved medications to provide relief has been documented; [t]he symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs; [s]uch treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness, and; [i]nvolves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.

IOM Report at 179. While the IOM's statement ostensibly would limit the use of cannabis to six months' duration, in the context of the full report it is apparent that the IOM does not urge the automatic termination of treatment at an arbitrary date, but rather recommends that patients' cannabis use be reevaluated on at least a biannual basis. The authors' reluctance to approve the longer-term use of cannabis was based primarily on their concern about the possible pulmonary risks posed by cannabis.

b. The House of Lords

While the IOM was conducting its evaluation, Britain's House of Lords was questioning and taking testimony from leading researchers, clinicians and patients regarding the medical benefits and drawbacks of cannabis. The House of Lords' report was issued in November 1998. Select Committee on Science and Technology, House of Lords, Sess. 1997-98, 9th Report, Cannabis: The Scientific and Medical Evidence: Report (hereinafter "Lords Report").

The findings and recommendations of the Lords Report closely parallel those of the IOM. Like the IOM, the House of Lords determined that cannabis holds important medical benefits for certain seriously ill patients for whom conventional therapies are ineffective.

The House of Lords, however, went a step further than the IOM. On the basis of its assessment of the medical benefits of cannabis, the House of Lords recommended that the government of Britain:

> transfer cannabis and cannabis resin from Schedule I of the Misuse of Drugs Regulations to Schedule 2, so as to allow doctors to prescribe an appropriate preparation of cannabis, albeit as an unlicensed medicine[6] and on the named-

[6] The United Kingdom, unlike the U.S., allows physicians to prescribe an unapproved medicine to a particular patient, so long as the physician provides the patient's name to the manufacturer. The Lords Report points out that a physician who prescribes cannabis on these terms must be aware of conditions for which cannabis might be contraindicated and inform patients of the possible effects on driving and cognitive function. Lords Report at § 8.16

patient basis, and to allow doctors and pharmacists to supply the drug prescribed.

Lords Report at § 8.23 (iii).

2. Cannabis Provides Essential Relief from Pain, Nausea, Anorexia, Muscle Spasticity and Seizures.

Pain: Neuropathic pain is a symptom commonly associated with a variety of illnesses or conditions, including metastic cancer, HIV/AIDS, multiple sclerosis (MS) and diabetes, and can also be a side effect of the recommended treatments for various conditions. Over 30% of patients with HIV/AIDS suffer from excruciating pain in the nerve endings (polyneuropathies), many in response to the antiretroviral therapies that constitute the first line of treatment for HIV/AIDS. Yet there is no approved treatment for such pain that is satisfactory for a majority of patients.[7] As a result, some patients must reduce or discontinue their HIV/AIDS therapy because they can neither tolerate nor eliminate the debilitating side effects of their first-line medications.

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[7] See, e.g., D. Simpson et al., Selected Neurologic Manifestations of HIV Infection: Dementia and Peripheral Neuropathy, Improving the Management of HIV Disease Vol. 7, Dec. 1999; N. Quang-Cantagrel et al., Opioid Substitution to Improve the Effectiveness of Chronic Noncancer Pain Control: a Chart Review, 90 Anesthesia and Analgesia 933 (2000) (reporting opioid analgesics are effective for only 36% of patients, ineffective for 34%, and intolerable for 30% of patients); Neurologic AIDS Research Consortium, Peripheral Neuropathy, http://www.neuro.wustl.edu/narc/peri-neuropathy.html ("Treatment of neuropathic pain...is notoriously difficult...[e]ven narcotics may not fully relieve [it].")

Patients with various pain syndromes, particularly neuropathic pain, claim significant relief from cannabis. See, e.g., Lords Report at §§ 5.26-5.30; L. Grinspoon & J. Bakalar, MARIJUANA: THE FORBIDDEN MEDICINE 109-26 (1997) [hereinafter "FORBIDDEN MEDICINE"]. The validity of their experiences is corroborated by studies in which cannabinoids have been shown to be effective analgesics in animal pain models. See, e.g., W. Martin, Basic Mechanisms of Cannabinoid-Induced Analgesia, International Association for the Study of Pain Newsletter (Summer 1999) ("There is now unequivocal evidence that cannabinoids are antinociceptive in animal models of acute pain").

Nausea, Anorexia and Wasting: Nausea, anorexia, and wasting are common symptoms of many cancers and AIDS.[8] They are also the common adverse side effects of chemotherapy and other aggressive therapies used to treat those diseases and associated pain.[9] Certain individuals, though, do not respond to currently available antiemetics. See, e.g., Declaration of Dr. Marcus Conant, J.A. at 101 (conventional drugs fail to relieve severe nausea and vomiting for some patients); Declaration of Dr. Howard Maccabee, J.A. at 110 (same); Declaration of Dr. Lester Grinspoon, J.A. at 127-128 (about half of patients treated with anticancer drugs suffer from severe nausea and vomiting; many of these patients find little or no relief in conventional antiemetics); IOM Report at 157 ("[f]ew

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[8] See, e.g., IOM Report at 151 (observing that patients receiving aggressive chemotherapy have "a 20-30 percent likelihood of experiencing acute emesis.")

[9] The nausea-inducing properties of opioid analgesics used to treat pain are uncontroverted. See, e.g., American Medical Ass'n, ENCYCLOPEDIA OF MEDICINE 98 (C. Clayman ed., 1989) ("Nausea [and] vomiting . . . may occur with narcotic analgesic drugs."); THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1223 (R. Berkow ed., 16th ed. 1992) (same).

therapies have proven successful in the treatment of the AIDS wasting syndrome.")

Herbal cannabis has been proven to provide critical relief for persons suffering from acute or chronic nausea and vomiting, but who do not respond to conventional therapies. Cancer patients undergoing chemotherapy, persons with HIV/AIDS taking antiretroviral drugs, and patients in severe pain who are prescribed nausea-inducing opioid analgesics comprise many members of this class. As the Institute of Medicine explains, "[t]he critical issue is not whether marijuana or cannabinoid drugs might be superior to the new drugs, but rather whether there is a group of patients who might obtain added or better relief from marijuana or cannabinoid drugs." IOM Report at 153. The IOM unequivocally answers this question in the affirmative:

> . . . It is possible that the harmful effects of smoking marijuana for a limited time might be outweighed by the antiemetic benefits of marijuana, at least for, patients for whom standard antiemetic therapy is ineffective and who suffer from debilitating emesis. Such patients should be evaluated on a case by case basis and treated under close medical supervision.

Id. at 154. See also Lords Report at § 5.12 (finding cannabis effective in alleviating acute nausea and vomiting).

The IOM's conclusion is supported by a significant body of clinical research and experience. In 1988, a New York State-sponsored study examined the effects of herbal cannabis on cancer chemotherapy patients who were unresponsive to standard antiemetics. Seventy-eight percent responded positively to cannabis. V. Vinciguerra et al., Peer

Reviewed Results of New York State-Sponsored Cancer/Marijuana Studies, 88 New York State J. of Med. 525 (1988). Several other states have undertaken similar trials with similar results. See generally R. Musty and R. Rossi, Effects of Smoked Cannabis and Oral Delta-9-Tetrahydrocannabinol on Nausea and Emesis After Cancer Chemotherapy: A Review of State Clinical Trials, 1 J. of Cannabis Therapeutics 29 (2001).[10] A 1991 survey of 2000 oncologists reported that 40% of the respondents considered cannabis to be therapeutically useful and would prescribe it if it were lawful to do so. R. Doblin and M. Kleiman, Marijuana as Antiemetic Medicine: A Survey of Oncologists' Experiences and Attitudes, 14 J. of Addictive Diseases 5 (1991). See also Declaration of Dr. Howard Maccabee, J.A. at 110; FORBIDDEN MEDICINE at 23-45.

Similarly, cannabis affords essential relief to patients suffering from anorexia and wasting syndromes for whom no other medications have worked. See IOM Report at 157 ("[Cannabinoids] could . . . be beneficial for a variety of effects, such as increased appetite, while reducing the nausea and vomiting caused by protease inhibitors and the pain and anxiety associated with AIDS."); Lords Report at § 5.15 (noting cannabis can counteract anorexia and wasting); Dec. of Dr. Marcus Conant, J.A. at 100-101 (same); FORBIDDEN MEDICINE at 100-09. See also Conant v. McCaffrey, 2000 U.S. Dist. LEXIS 13024, *12-13 (N.D. Cal. 2000) (describing AIDS patient suffering from life-threatening wasting syndrome who needs herbal cannabis to stimulate appetite).

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[10] These studies took place before the introduction of current, more powerful, antiemetic drugs, such ondansetron (Zofran) and granisetron (Kytril). However, as noted in the IOM Report, a significant percentage of patients still do not respond to these newest drugs. IOM Report at 151.

Muscle Spasticity: As the IOM Report notes, current treatments for painful muscle spasms, commonly associated with multiple sclerosis and spinal cord injuries, have only limited effectiveness and their use is complicated by various adverse side effects. Id. at 164. A growing body of clinical and preclinical literature demonstrates that cannabinboids are effective in controlling the debilitating symptoms of multiple sclerosis ("MS"). See D. Baker et al., Cannabinoids Control Spasticity and Tremor in a Multiple Sclerosis Model, 404 Nature 117 (Mar. 2, 2000); Lords Report at §§ 5.19-5.23. For example, while conventional treatments have limited effectiveness for bladder dysfunction and pain associated with MS, see IOM, MULTIPLE SCLEROSIS: CURRENT STATUS AND STRATEGIES FOR THE FUTURE (2000) at 149, 171, cannabis has been shown to be effective in alleviating these problems. Lords Evidence at 31-43. In addition, a survey of British and American MS patients reports that after ingesting herbal cannabis a significant majority experienced substantial improvements in controlling muscle spasticity and pain.[11] In one case study, herbal cannabis provided relief from both muscle spasms and ataxia (loss of coordination), a multiple benefit not achieved by any currently available medications.[12] Many MS patients also report that the relief afforded by cannabis has allowed them to discontinue many of the conventional medications that caused debilitating side effects. See FORBIDDEN MEDICINE at 80-94.

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[11] P. Consroe et al., The Perceived Effects of Smoked Cannabis on Patients With Multiple Sclerosis, 38 European Neurology 44 (1997) (reporting 91-98% of respondents experienced lessened nighttime spasticity and muscle pain, and 71-74% of respondents reported decreased night leg pain, depression, tremor, anxiety, spasms on walking, leg weakness, trunk numbness, and facial pain).

[12] H. Meinck et al., Effect of Cannabinoids on Spasticity and Ataxia in Multiple Sclerosis, 236 J. of Neurology 120 (1989).

Seizures: Clinical experience and emerging research further indicate that cannabis can help control epileptic seizures. Lords Report at § 5.31; FORBIDDEN MEDICINE at 66-80. Cannabidiol (CBD), one of the primary (and non-psychoactive) cannabinoids present in the cannabis plant, appears to be of particular benefit, allowing patients who ingest it in the auric phase of a seizure to avoid seizure activity. Some epileptics who cannot tolerate conventional anti-seizure medications have been able to use cannabis to successfully control their seizures, absent debilitating side effects. See J. Cunha, Chronic Administration of Cannabidiol to Healthy Volunteers and Epileptic Patients, 21 Pharmacology 175 (1980); Declaration of Dr. Lester Grinspoon, at 76-79. See also Regina v. Parker [2000] 75 C.R.R. (2d) 233 (holding that epileptic who suffered "frequent serious and potentially life-threatening seizures" and for whom surgery and conventional medications were unsuccessful is entitled to take herbal cannabis to control seizures notwithstanding the prohibition of medicinal cannabis use under Canadian drug control statutes).

As these studies and reports demonstrate, where conventional therapies are unsatisfactory for seriously ill patients, herbal cannabis can provide a restorative, sometimes life-saving alternative. In such instances, it is both ethical and legitimate for physicians to recommend and patients to choose such treatment.

B. The Side Effects of Medicinal Cannabis are Often Less Severe Than Those of Conventional Medications.

As an initial matter, it is important to note that this case concerns the narrow class of people who meet the

definition of medical necessity, meaning that they have no other alternative to relieve their pain and suffering. Further, as the warnings that accompany numerous over-the-counter and prescription medications make clear, the Food and Drug Administration approves, and physicians order, medications that can cause debilitating, even fatal reactions in persons who ingest them. Against this backdrop, there is significant evidence that cannabis "is safer, with fewer serious side effects than most prescription medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics." Declaration of Dr. Lester Grinspoon, J.A. at 136.

The Institute of Medicine examined the various potential harms associated with the medical use of cannabis and determined that "the adverse effects of cannabis are within the range tolerated for other medications." IOM Report at 127-28. Indeed, cannabis is considered to have a very wide margin of safety, see Regina v. Parker, 75 C.R.R. (2d) at *48-49 (noting wide margin of safety of, and no evidence of overdose fatality from cannabis), whereas even the most commonly used synthetic analgesics – aspirin, acetaminophen (Tylenol), and nonsteroidal anti-inflammatory drugs like ibuprofen – are attributed with causing as many as 76,000 hospitalizations and more than 7,600 deaths annually. FORBIDDEN MEDICINE at 109.

Immune system: Of particular import to individuals with HIV/AIDS, cannabis shows no indication of having an immuno-suppressant effect. See IOM Report at 110. A recent study by Dr. Donald Abrams at the University of California San Francisco confirms that the use of cannabis does not adversely affect the immune system of HIV patients taking antiretroviral therapies. See D. Abrams, Short Term Effects of Cannabinoids on HIV-1 Viral Load, presented at

the 13th International AIDS Conference at Durban, South Africa (July 2000).[13]

Cardiovascular system: The ingestion of cannabis raises the heart rate, but there is no evidence that this increase poses a risk of cardiac arrest in patients who do not have pre-existing heart problems. See IOM Report at 121.

Pulmonary system: As for pulmonary effects, smoked herbal cannabis unquestionably causes tars to be introduced into the respiratory tract. Like for smokers of tobacco, studies have suggested that cannabis smokers have a greater number of cellular and molecular abnormalities in the bronchial epithelium cells than nonsmokers, and that these changes are associated with an increased cancer risk. S. Barsky et al., Histopathologic and Molecular Alterations in Bronchial Epithelium in Habitual Smokers of Marijuana, Cocaine, and/or Tobacco, 90 J. of the National Cancer Institute 1198 (1998). On the other hand, "[t]here is conflicting evidence on whether regular marijuana use harms the small airways of the lungs." IOM Report at 115. Thus, it is uncertain whether smoking cannabis, particularly for patients who may only consume enough to mitigate their symptoms, can actually cause pulmonary harm, such as chronic obstructive pulmonary disease (COPD) or lung cancer. See L. Zimmer and J. Morgan, MARIJUANA MYTHS, MARIJUANA FACTS 113-15 (1997); S. Sidney et al., Marijuana Use and Cancer Incidence, 8 Cancer Cause and Control 722 (1997).

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[13] Cannabis can contain viable fungal spores, which can pose a hazard for patients with compromised immune systems. However, cannabis can be easily sterilized in a home oven at 300 degrees Fahrenheit, for five minutes to kill spores without degrading or vaporizing the THC. J. McPartland and P. Pruitt, Medical Marijuana and Its Use by the Immunocompromised, 3 Alternative Therapies 39, 43 (1997).

Psychological effects: *Amici* for the government would like this Court to believe that this case is about letting more people get "high." Nothing could be further from the truth. In fact, for seriously ill patients, who are quite debilitated by disease, the euphoric effect sought by recreational users of cannabis is generally undesirable. Accordingly, they will seek a dose that is adequate to alleviate their symptoms but not so large as to cause mental impairment. IOM Report at 84. Indeed, researchers who study the therapeutic properties of cannabis regard a patient's "high" to be an indication of excessive intake. See Lords Evidence at 178.

Dependence: Patients who use cannabis on a chronic basis may develop mild physiological dependence and experience withdrawal symptoms, particularly if their cannabis use is discontinued abruptly. But these symptoms are "subtle, compared with the profound physical syndrome of alcohol or heroin withdrawal." IOM Report at 90.[14] And compared to tobacco and alcohol, dependence on cannabis is relatively rare. Id. at 94. To put the matter in perspective:

> Tolerance and dependence are normal physiological adaptations to repeated use of any drug. The correct use of prescribed medications for pain, anxiety, and even hypertension commonly produces tolerance and some measure of physiological dependence.

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[14] These symptoms include restlessness, irritability, mild agitation, insomnia, sleep EEG disturbance, nausea, and cramping. Id. at 90. The IOM Report stressed that this syndrome "has only been reported in a group of adolescents in treatment for substance abuse problems or in a research setting where subjects were given marijuana or THC on a daily basis [and then precipitously withdrawn from it]." Id. at 91 (citations omitted).

Id. at 84-86. In short, the medical use of cannabis, particularly by patients who meet the stringent criteria of the medical necessity defense, does not raise serious concerns of drug dependence.

C. For Many Seriously-Ill Patients, Marinol Does Not Offer a Satisfactory Treatment Alternative.

The federal government contends that Marinol, the brand name of dronabinol and a synthetic isomer of THC, offers "[o]ne method of delivery of cannabinoids." Brief of Petitioner at 41, n.18. Marinol, however, is not a satisfactory treatment alternative for many patients with serious and otherwise intractable conditions.

First, Marinol is composed of only a single compound, THC. By contrast, cannabis is a complex botanical substance, containing over 400 constituents and approximately 66 cannabinoids, which fall into 10 groups of closely related cannabinoids. The main cannabinoids include delta9-THC, delta8-THC, cannabidiol (CBD), cannabinol, cannabichromeme, and cannabigerol. IOM Report at 24-25. Several of these cannabinoids – not just THC – have therapeutic applications, either alone or in combination with others:

> Herbal cannabis contains a mixture of active compounds. It is too early to be certain if the therapeutic action is limited to one compound. . . . Cannabis may contain a synergistic mixture of active compounds. This is particularly likely now that we know

there are at least two receptor specified loci of action.

Lords Evidence at 32. See also J. McPartland, Side Effects of Pharmaceuticals Not Elicited by Comparable Herbal Medicines: The Case of Tetrahydrocannabinol and Marijuana, 5 Alternative Therapies 57, 60 (July 1999). For example, CBD, which is not psychoactive, has been shown to have potential neuroprotective and anti-inflammatory uses. See A. Hampson et al., Cannabidiol and (-) Delta-9-tetrahydrocannabinol are Neuroprotective Antioxidants, 95 Proceedings of the National Academy of Science 8268 (1998) (neuroprotection); A. M. Malfait et al., The Nonpsychoactive Cannabis Constituent Cannabidiol is an Oral Anti-Arthritic Therapeutic in Murine Collagen-Induced Arthritis, 17 Proceedings of the National Academy of Science 9561 (Aug. 2000) (anti-inflammatory/anti-arthritic effect).

Second, Marinol's onset of action is gradual and prolonged. Peak blood levels only are achieved 2-3 hours after ingestion. Indeed, Marinol's delayed onset is a primary reason that the government considers Marinol to have a low abuse potential. See 63 Fed. Reg. 59,751 (Nov. 5, 1998) (Notice of Proposed Rulemaking). As a result, patients in need of immediate relief must often suffer an extended period of time before Marinol takes effect. By contrast, smoking herbal cannabis – though by no means an ideal route of ingestion – is a more efficient delivery mechanism that provides the blood stream with the therapeutic properties of cannabis almost instantaneously resulting in prompt relief for patients. In the words of one of the principal investigators for the IOM Report, "[s]moking . . . delivers rapid drug effect, whereas the THC capsule takes effect slowly and its results are variable. There are many symptoms for which a quick-acting drug is ideal, such as

pain, nausea, and vomiting." Opening Statement of Stanley J. Watson, Jr., IOM News Conference March 17, 1999.

Third, smoking herbal cannabis, despite significant drawbacks, can be a more effective and less debilitating route of ingestion than swallowing a Marinol capsule. After being swallowed, Marinol is delivered first to the stomach and then to the liver where it is metabolized into 11-hydroxy-delta 9-THC. This metabolite is 3-4 times more psychoactive than THC delivered to the lungs by smoked cannabis. IOM Report at 36. Therefore, not only do patients on Marinol suffer a prolonged wait for relief, but also often experience harsh psychoactive side effects from ingesting a full-dose of THC that they are unable to mitigate. By contrast, patients who smoke herbal cannabis can regulate their dose of THC, achieving the desired therapeutic effect without experiencing a "high."

> Many patients report relief of symptoms at a dose short of those producing psychedelic effects. This is reminiscent of the treatment of cancer pain and post-operative pain with narcotics by PCA (patient controlled analgesia) where the patient titrates their pain down to a bearable level while still thinking clearly.

Lords Evidence at 31. As Dr. Roger Pertwee, a cannabinoid researcher states:

> [S]moking . . . is actually a very good route of administration, in some ways; it is very effective, there is a very rapid absorption, and the patients have a great deal of control over how much they take. They learn to titrate.

Lords Evidence at 73.[15]

Finally, Marinol has been approved for treatment of only two indications: nausea/vomiting associated with cancer chemotherapy in patients who have failed to respond adequately for conventional antiemetic agents and AIDS-related anorexia. 64 Fed. Reg 35,928 (1999). Because Marinol must be swallowed, however, it is exceedingly difficult for some severely nauseated patients to get or keep the capsules down. See Declaration of Dr. Howard Maccabee, J.A. at 110-111. Therefore, the "choice" of Marinol is in fact illusory for some of the most seriously ill patients.

D. Patients Cannot Obtain Meaningful Access to Cannabis Treatment Through "Alternative Options."

The federal government avers that desperate patients who seek to obtain relief from cannabis have abundant "options," other than obtaining cannabis privately after receiving the advice and approval of their physicians. The government suggests that such patients should 1) participate in a clinical trial; 2) wait until cannabis has been rescheduled; or 3) wait until a pharmaceutical-quality, nonsmoked cannabinoid product is available. For most suffering patients, these alternatives are meaningless.

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[15] As an alternative to smoking, the therapeutic components of the cannabis plant can be inhaled using vaporizer devices. Vaporizers heat cannabis to 150-200 degrees Centigrade, evaporating the cannabinoids and other volatile oils. This temperature is below the burning point of combustible plant material, so smoke is not generated. This technology has been available for over 20 years. McPartland and Pruitt, supra, at 43.

1. Few Patients Will be Able to Participate in Controlled Clinical Trials Involving Herbal Cannabis.

Controlled, double-blind clinical trials of new drugs are expensive to conduct. Therefore, researchers will pursue such studies only if they can obtain independent funding from a commercial sponsor, such as a pharmaceutical company, or from a grant-making entity, such as the government. But neither of these options is likely with respect to cannabis. As both the IOM and House of Lords reports note, pharmaceutical companies are unwilling to invest in clinical trials for smoked cannabis because the herbal plant would never be approved as a prescribable medicine:

> The market outlook in the U.S. is distinctly unfavorable for the marijuana plant and for cannabinoids found in the plant. Commercial interest in bringing them to market appears nonexistent.

IOM Report at 219. It is also unlikely that the government will support an adequate number of such trials. Despite the widespread interest in the subject, the National Institute of Health has funded only one clinical trial involving herbal cannabis in the last decade, and that study investigated the safety, rather than the efficacy, of its use.[16] Even for less controversial treatments, the chance of receiving NIH funding is small.[17] Only one state, California, has earmarked

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[16]See D. Abrams, Medical Marijuana: Tribulations and Trials, 30 Journal of Psychoactive Drugs 163 (1998).

[17] As the IOM Report states: "Research grant approvals are handled through the conventional NIH peer review process for extramural research, a highly competitive process with success rates in 1997 of 32%

funds to research the therapeutic effects of cannabis[18], and some of those funds may be spent on animal or *in vitro* studies. Only one county in the United States, San Mateo, California, has provided some funding for clinical research with medicinal cannabis, but that funding cannot support extensive ongoing.[19]

Even if there were an unlikely increase in the number of clinical trials of herbal cannabis, a very limited number of patients would be able to participate in these trials due to geographical restrictions or disease or symptom specificity of the research. Further, even if several trials secured government or private funding, it is not clear that the federal government – the sole lawful source in the United States for herbal cannabis – would be willing or able to provide researchers with a sufficient supply of the cannabis plant. The University of Mississippi, under exclusive contract with the National Institute on Drug Abuse (NIDA), produces all herbal cannabis for U.S. research trials. IOM Report at 213. The stocks have historically been primarily allocated to research investigating herbal cannabis as a drug of abuse and only incidentally to research investigating its therapeutic

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of approved NIDA grants. . . . In 1998, less than 25% of **all** first time investigator-initiated grant applications . . . to the NIH were funded." IOM Report at p. 214.

[18] In 1999, SB 847 codified at Health & Safety Code § 11362.9, established, but did not fund, a three-year cannabis research program to be housed within the University of California. In 2000 the legislature appropriated and the governor approved $3 million for the program's first year. Funding for future years is uncertain.

[19] The $350,000 will fund a single 12 week study involving 60 patients. Local Pot Study Sought, San Jose Mercury News, Dec. 26, 1999.

efficacy. . See, e.g., http://www.nih.gov/grants/award/award.htm.[20]

2. The Federal Government Refuses to Provide Herbal Cannabis for Controlled Clinical Trials Involving Single Patients.

Patients who would qualify under a medical necessity defense for the use of herbal cannabis may not be eligible to participate in standard clinical trials involving herbal cannabis. Their medical conditions may be too rare or idiosyncratic to warrant even a small-scale clinical trial. Or they may live too far from the location of the nearest trial to make the frequent trips to the clinic or hospital required by many protocols. Alternatively, they may not be able to leave their families or jobs and remain sequestered in a hospital for the duration required by other clinical protocols.

Such patients nevertheless may be good candidates for "n-of-1" trials; that is, trials involving the efficacy of the drug as to a single individual. The validity and usefulness of n-of-1 trials is well documented.[21] Like larger-scale studies, n-of-1 studies are subject to the requirements of randomization and double-blinding, but each patient serves as his or her own control. This research design allows

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[20] The first researcher who attempted to obtain cannabis for research purposes under NIDA's revised cannabis access policy was denied access to the material notwithstanding the fact that his research proposal had been approved by the FDA. Letter from Dr. Steven Gust, Special Assistant to the Director (NIDA) to Dr. Ethan Russo of 2/1/00.

[21] See, e.g., E.B. Larson et al., Randomized clinical trials in single patients during a 2-year period, 270 J. of the Am. Med. Ass'n 2708 (1993); D. Cook, Randomized Trials in Single Subjects: the N of 1 Study, 32 Psychopharmacology Bull. 363 (1996).

investigators to examine a particular experimental therapy with an eye to fashioning larger-scale trials.[22] In addition, n-of-1 studies enable physicians to better respond to case-specific circumstances of patients by modifying treatment regimens.[23]

For these reasons, the IOM Report advocates n-of-1 trials for this patient population:

> Until a non-smoked, rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that **there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana**, such as pain or AIDS wasting. One possible approach is to treat patients as n-of-1 clinical trials, in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision, thereby increasing the knowledge base of the risks and benefits of marijuana use under such conditions. **We recommend these "n-of-1" clinical trials** .

IOM Report at 179-80 (emphases added).

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[22] See, e.g., R. Van Reekum et al., N of 1 Study: Amantadine for the Amotivational Syndrome in a Patient With Traumatic Brain Injury, 9 Brain Inj. 49 (1995).

[23] See e.g., E. Wiebe, N of 1 Trials: Managing Patients With Chronic Fatigue Syndrome: Two Case Reports, 42 Can. Fam. Physician 2214 (1996).

Yet despite the support for n-of-1 studies in the scientific literature and the recommendation of the IOM, the U.S. Department of Health and Human Services ("HHS") rejected this design for studies involving herbal medicinal cannabis. On May 21, 1999, HHS published an "Announcement of the Department of Health and Human Services Guidance on Procedures for the Provision of Marijuana for Medical Research."[24] In the Department's words, "the single-patient IND [investigative new drug] process would not produce useful scientific information, and we do not foresee that they would be supported under this program." Id. The rejection by HHS of n-of-1 studies deprives many patients of access to medicinal cannabis within a bona fide research project.

3. Pharmaceutical-Quality, Nonsmoked Cannabis Medicines Are Years Away from Development and Marketing.

The IOM Report describes the obstacles that any pharmaceutical company would face when undertaking the kind of research and development program with herbal cannabis that would be required for FDA approval. The costs of development are substantial, and the uncertainty of rescheduling a product developed from the plant creates a deterrent to investment. By contrast, Marinol was developed and marketed with substantial support from the federal

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[24] According to HHS policy, cannabis would be made available to only approved research projects. However, the policy establishes an additional hurdle for independently-funded researchers, who must have their clinical protocols approved not only by the FDA, but also by an ad hoc panel of the Public Health Service, which employs separate approval criteria. Normally, an independent researcher must only have his or her protocol approved by the FDA.

government.[25] It is extremely unlikely that an herbal cannabis product would receive the extensive governmental assistance conferred upon Marinol. As an additional obstacle, potential patent protection for materials derived from naturally-occurring plants may be quite limited. Thus, the lack of commercial interest is not surprising. The IOM Report concludes:

> . . . the development of the marijuana plant is beset by significant scientific, regulatory, and commercial obstacles and uncertainties. The prospects of its development as a new drug are unfavorable, unless return on investment is not a driving force. It is noteworthy that no pharmaceutical firm has sought to bring it to market in the U.S.

Id. at 219.

Even if a pharmaceutical company were to begin developing a pharmaceutical-quality cannabis medicine administered through a rapid-onset alternative (i.e., nonsmoked) delivery mechanism, it would take several years to obtain marketing approval in the U.S.[26] Depending on the delivery mechanism used, the product might require approval

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[25] Preclinical and clinical research on Marinol were largely supported by the National Cancer Institute. The scheduling of Marinol was expedited by the DEA, which scheduled the drug before the FDA approved it for marketing. IOM Report at 202-03. Moreover, the FDA did not require the manufacturer to perform costly abuse liability studies, id., thus dramatically reducing the time and cost of bringing Marinol to market. Id. at 218.

[26] Only one small British pharmaceutical company, GW Pharmaceuticals Ltd., has begun to develop cannabis-based medicines derived from the whole plant. See www.medicinal-cannabis.org. This company has not yet begun a formal development program in the U.S.

under both the new drug and device processes set out in federal law. See 21 C.F.R. Part 3 (combination products). In short, any suitable pharmaceutical alternative to herbal cannabis will not come to market for several years, if at all.

4. The Prospect of the Rescheduling of Herbal Cannabis is Remote and Uncertain.

The federal government also suggests that suffering and dying patients have the option of waiting until herbal cannabis is removed from Schedule I of the CSA. To date, however, such rescheduling efforts have encountered years of delay in proceeding through the administrative gauntlet. In 1972, the National Organization for the Reform of Marijuana Laws sought to reschedule cannabis. After 22 years of litigation, that effort failed. Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C.Cir. 1994).

In July 1995, Jon Gettman filed a petition seeking the rescheduling of cannabis based on new developments in scientific knowledge. After five and one-half years, that petition has still not emerged from the Department of Health and Human Services. Even if HHS were to recommend that herbal cannabis should be rescheduled, its recommendation would not be binding on the Drug Enforcement Administration, which would undertake its own evaluation based on factors set forth in 21 USC § 811. Even if successful, these processes would not be completed in time to bring relief to the clients of the Oakland Cannabis Buyers' Cooperative who currently meet the stringent medical necessity criteria for herbal cannabis.

V. CONCLUSION

For the foregoing reasons, the judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

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APPENDIX

APPENDIX

Amicus Curiae American Public Health Association ("APHA"), founded in 1872, is the largest public health organization in the world, representing over 50,000 public health professionals. A national organization, APHA is devoted to the promotion and protection of personal and environmental health. It represents all disciplines and specialties in public health, including maternal and child health and substance abuse. APHA strives to improve public health for everyone by proposing solutions based on research, helping to set public health practice standards, and working closely with national and international health agencies

Amicus Curiae California Nurses' Association ("CNA") is the largest organization of Registered Nurses in California, representing 31,000 members in more than 100 hospitals, clinics, and home health agencies. Over the past decade CNA has been one of the fastest growing health care unions in the nation, earning a national reputation for its efforts in the field of regulatory reform and patient advocacy. It is in light of the experiences of its constituent members, who work daily on the front lines not only with seriously ill patients but also with the latest medicines and medical technologies, that CNA endorses medical cannabis as a legitimate treatment option for certain seriously ill patients.

Amicus Curiae Lymphoma Foundation of America is a national nonprofit organization devoted to helping lymphoma patients and their families. An estimated 62,000 new cases of lymphoma (cancers of the lymph system) will be diagnosed this year. It is the Lymphoma Foundation's experience, over many years, with thousands of patients, that marijuana is an efficacious and at times necessary treatment

for nausea, vomiting, and lack of appetite – serious, sometimes life-threatening symptoms that afflict many lymphoma patients undergoing chemotherapy and radiation.

Amicus Curiae Irvin Henry Rosenfeld was diagnosed at age 10 with multiple congenital cartilogenous exostosis, a disease causing the continuous growth of bone tumors, and the generation of new tumors, on ends of most of the long bones in his body. He was told he would not survive into adulthood. In an attempt to treat the painful symptoms of this disease, he was prescribed high doses of opioid analgesics, muscle relaxants and anti-inflammatory medications which he took on a daily basis, but which had minimal efficacy and produced debilitating side effects. In 1971, Mr. Rosenfeld began using smoked herbal cannabis with the approval and under the supervision of a team of physicians. Mr. Rosenfeld found the cannabis highly efficacious in alleviating pain, reducing swelling, relaxing muscles and veins that surround the bone tumors, and preventing hemorrhaging. In 1982, the United States government, operating under the Compassionate Care IND Program, at the request of his physicians, began supplying Mr. Rosenfeld with herbal cannabis to treat his condition. For the past 19 years, the government has consistently provided him with a 75-day supply of herbal cannabis, totaling 33 ounces per shipment. Mr. Rosenfeld smokes 12 marijuana cigarettes a day to control the symptoms of his disease. In the 30 years that Mr. Rosenfeld has used herbal cannabis as a medicine, he has experienced no adverse side effects (including no "high"), has been able to discontinue his prescription medications, and has worked successfully for the past 13 years as a stockbroker handling multi-million dollar accounts. Mr. Rosenfeld and his physicians believe that but for herbal cannabis, Mr. Rosenfeld might not be alive, or, at the very least would be bed-ridden.

Amicus Curiae Barbara M. Douglass was diagnosed with Multiple Sclerosis in 1988 at the age of 22. In 1991, Ms. Douglass began receiving herbal cannabis from the United States government upon the advice and assistance of her physician. Prior to this date, Ms. Douglass had never tried cannabis. Each month, the government provides her physician with one can containing three hundred cannabis cigarettes, each weighing 7/10 oz. Ms. Douglass and her physician report that herbal cannabis provides relief from pain, spasms, and stimulates her appetite to counteract the effects of wasting syndrome from which she suffered prior to using cannabis. Ms. Douglass has never experienced any adverse side effects from marijuana. Without cannabis, Ms. Douglass believes she would not be alive today.

Amicus Curiae Elvy Musikka was diagnosed with glaucoma in 1975 at the age of 36. She tried conventional medications to treat her condition, but could not tolerate them. Reluctantly, in 1976, she decided to try herbal cannabis at the advise of her physician. The cannabis provided her immediate relief, substantially lowering her intraocular pressure as no other medication had, and with few side effects. Ms. Musikka ingests cannabis by smoking it, as well as eating it in baked goods and olive oil. Fearful of the legal consequences of smoking cannabis, Ms. Musikka underwent several risky surgeries in an attempt to correct her condition, but they were unsuccessful and left her blind in one eye. In 1988 Ms. Musikka was arrested in Florida and charged with cannabis possession. She challenged her conviction in the Florida Supreme Court where she prevailed, becoming the first person in that state to establish a medical necessity defense for cannabis. Shortly thereafter, the federal government enrolled Ms. Musikka in its medical cannabis program and has provided her with one and one-half pounds of herbal cannabis on a quarterly basis ever since. Mrs.

Mussika and her physician believe that if she were deprived of cannabis she would go blind.

Amicus Curiae George Lee McMahon was born July 22, 1950 with Nail Patella Syndrome, a rare genetic disorder that causes severe pain, nausea and muscle spasms. Mr. McMahon tried conventional medications to treat his symptoms, but found the side effects of these medications to be intolerable. In the early 1980's Mr. McMahon discovered that herbal cannabis alleviated his pain, nausea and spasms, stimulated his appetite and allowed him to sleep through the night. In 1988 Mr. McMahon informed his physician that he was successfully self-medicating with cannabis. His physician ordered him to cease his cannabis use and return to prescription medications. Over the following six months, Mr. McMahon's health progressively degenerated. Mr. McMahon's physician then helped Mr. McMahon apply to the federal government's Compassionate Care IND Program. In March 1990, Mr. McMahon was accepted into the program and for the past decade has received 300 cannabis cigarettes each month from the United States government. Mr. McMahon and his physician believe that without cannabis Mr. McMahon would not be alive today.

Amicus Curiae American Medical Women's Association ("AMWA") is a national, non-profit organization of over 10,000 women physicians and physicians-in-training representing every medical specialty. Founded in 1915, AMWA is dedicated to promoting women in medicine and advocating for improved women's health policy.

Amicus Curiae Colorado Nurses' Association ("CNA") is a professional organization of registered nurses in Colorado and is a constituent of the American Nurses' Association. The primary purpose of this association for the past 90 years has been to provide direction and a voice for the profession

of nursing and nurses as leaders in health care, and to work for the improvement of health standards and the availability of health care services for all people.

Amicus Curiae AIDS Treatment Initiatives ("ATI") is a nonprofit organization devoted to enhancing the quality of life and extend long-term survival for people living with HIV disease through treatment education, treatment advocacy, and access to complementary therapies. ATI accomplishes this mission through nutrition and adherence counseling services, symptom and side effect management, and adjunct consulting services to primary care physicians. ATI was incorporated in 1991 and supports an active client caseload of 1,200 client members. ATI's primary geographic focus is the Southeastern United States but nationally serves client members located throughout the United States.

Amicus Curiae AIDS Resource Center of Wisconsin ("ARCW"), through its Legal Services Program, provides direct legal representation to hundreds of persons living with HIV and AIDS throughout the entire state of Wisconsin at no charge to the clients. In addition handling a variety of legal matters including HIV confidentiality, social security benefits, employment matters and estate planning, ARCW pursues impact litigation and public advocacy projects.

Amicus Curiae AIDS Project Arizona is an organization dedicated to stopping the transmission of HIV, empowering infected persons to live longer, healthier lives and providing an innovative, comprehensive continuum of services for individuals and families affected by the disease.

Amicus Curiae Mothers Against Misuse and Abuse (MAMA) is a non-profit organization founded in 1982, which provides an educational approach to the many aspects of substance use. In today's society, in addition to problems

with illegal drugs, there are high levels of alcohol abuse, prescription drug misuse and abuse, and great harm caused by excessive consumption of nicotine, caffeine and over-the counter drugs. MAMA offers guidelines for evaluating a drug's benefits and risks, including both health risks and legal risks. MAMA's goals are to promote better communication; to provide current, scientific drug education to all ages of society; and to advocate for appropriate treatment, including the use of medical marijuana for seriously ill patients.

Amicus Curiae Marin County Medical Society of California is an organization representing 400 members and whose purpose is to promote and develop the science and art of medicine and the care and well-being of patients; to conserve and protect the health of the public; to promote the betterment of the medical profession; to cooperate with groups of like purposes and to unite with similar organizations in the formation and activities of the California Medical Association.

Amicus Curiae The Gay and Lesbian Medical Association (GLMA) is a tax-exempt 501(c)3 non-profit organization working to end homophobia in healthcare. Our membership of 2,000 medical professionals represents the interests of more than 70,000 lesbian, gay, bisexual, and transgender (LGBT) physicians and medical students, as well as millions of LGBT patients throughout North America who seek equality in healthcare access and delivery. GLMA promotes quality health care for LGBT and HIV-positive people, including access to medical marijuana for seriously ill patients.

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UNITED STATES OF AMERICA,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, *ET AL.*,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF THE NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS AND NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI*[1]

The National Organization for the Reform of Marijuana Laws (NORML) was organized in 1970, and participates in the public policy debate over marijuana policy for the tens of millions of adult Americans who use marijuana responsibly. NORML lobbies for the rights of marijuana users and other taxpayers and voters who oppose current prohibition policies. NORML has more than 5,000 financial supporters from every state. It also has a grassroots political network of more than 18,000 volunteer activists, including 60 state and local affiliated organizations, who oppose the criminal prohibition of marijuana.

NORML has long supported policies that would permit seriously ill patients to use cannabis as a medicine with a recommendation from their physician. NORML opposes the use of marijuana by children and adolescents, and has published a set of guidelines for responsible marijuana smoking entitled "Principles of Responsible Cannabis Use."[2]

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[1] Pursuant to S.Ct. Rule 37.6, counsel certifies that no counsel for a party authored any part of this brief. No person or entity other than *amici* made a monetary contribution to the preparation or submission of the brief.

Pursuant to S.Ct. Rule 29.6, both NORML and NACDL are nonprofit corporations. Neither has a parent corporation, and neither is a publicly held corporation, nor does a publicly held company own 10% or more of their stock.

[2] Some of the *amici curiae* supporting the federal government claim that supporters of the medical use of cannabis, such as NORML, use the issue as a ruse to build support for the decriminalization or legalization of recreational marijuana smoking. NORML supports both legalizing the

NORML asserted the medical use of cannabis in 1972 in an administrative petition asking the federal government to move cannabis from schedule I to schedule II of the Controlled Substances Act so doctors could prescribe it. After years of administrative litigation, a DEA Administrative Law Judge found in 1988 that:

> Marijuana has been accepted as capable of relieving distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.[3]

The ALJ there recommended "that the Administrator transfer marijuana from Schedule I to Schedule II, to make it available as a legal medicine." *Id.* The Administrator of the DEA rejected this conclusion, and the Court of Appeals for the District of Columbia Circuit affirmed,[4] effectively denying medical cannabis to seriously ill patients, except for the DEA's own Compassionate IND program. In the past 20 years, NORML has several times

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medical use and the recreational use of marijuana, but recognizes that they are two distinct issues and each has to be evaluated as a public policy option on its own merits. There are millions of Americans, for example, who support the medical use of cannabis (*see* the polling data in Appendix A) but who oppose legalizing marijuana for recreational use. Speculation about ulterior motives is irrelevant to the impact of the requested injunction on seriously ill patients with their doctor's consent, whose quality of life depends on medical cannabis.

[3] *In The Matter of Marijuana Rescheduling Petition*, Docket No. 86-22 (Sept. 6, 1988).

[4] *Marijuana Scheduling Petition*, 54 Fed.Reg. 53767, 53784 (Dec. 29, 1988), *aff'd Alliance for Cannabis Therapeutics v. DEA*, 304 U.S.App.D.C. 400, 15 F.3d 1131 (1994).

litigated the issue of medical use of cannabis in federal courts.[5] With reclassification blocked by the DEA, NORML has continued to advocate the medical use of cannabis and to support state and federal legislation and voter initiatives to that end.

The National Association of Criminal Defense Lawyers (NACDL) is the preeminent bar organization advancing the mission of the nation's criminal defense lawyers to ensure justice and due process for persons accused of crime. Founded in 1958, NACDL has more than 10,000 direct members and 80 state and local affiliate organizations with 28,000 members committed to preserving the Bill of Rights. The American Bar Association recognizes NACDL as an affiliate organization on its House of Delegates. NACDL promotes study and research in the field of criminal law. In furtherance of its objectives over the past decade, NACDL files approximately ten *amicus* briefs a year with this Court on criminal justice issues.

The parties have consented to NORML and NACDL filing this *amici* brief on behalf of the respondents, and the letters of consent are filed with this brief.

SUMMARY OF ARGUMENT

I.A. This case is not about a right to get "stoned," as petitioner's *amici* would suggest. Instead, it is about the

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[5] NORML has always been a party in the "marijuana rescheduling" cases seeking federal recognition of the medical use of cannabis. *See, e.g.*, the related cases of *Alliance for Cannabis Therapeutics v. DEA*, note 4 *supra*; *Alliance for Cannabis Therapeutics v. DEA*, 289 U.S.App.D.C. 214, 930 F.2d 936 (1994); *NORML v. DEA*, 182 U.S.App.D.C. 114, 559 F.2d 735 (1977); *NORML v. Ingersoll*, 162 U.S.App.D.C. 67, 497 F.2d 654 (1977).

confluence of state and individual rights: A state's capacity to legislate its public health policy by choosing its own means and ends to achieve what it believes best for the good of its people when there is no superior competing federal interest; and, the right of personal medical choices of the chronically and terminally ill, made in consultation with doctors. This state-federal conflict implicates several individual liberties intertwined under our Constitution: The right of the "pursuit of happiness" and liberty by the chronically and terminally ill; the right of citizens "to be let alone" by government in personal decisions; and substantive due process when there is no comparable federal interest in prohibiting the conduct at issue.

B. Many sick people are not helped by conventional drug therapy for serious medical conditions. The medical use of cannabis has been recognized for 5,000 years. Hundreds of articles, books, and reports deal with the efficacy of cannabis for medicinal use. Nine states with 20.51% of the nation's population have legalized the medical use of cannabis.

II.A. No form of legislation is more fundamental than the right of the people of the American states to enact laws by initiative. This power is reserved to the people and the states under the Ninth and Tenth Amendments. In the nine states where the people have determined by their political and legislative processes that medical use of cannabis for the chronically or terminally ill is a right and a choice made between doctor and patient, medical cannabis is elevated by their public policy to a privacy and due process right. The federal government has a duty to respect these states' decisions, and it has no law enforcement or public safety interest in criminalizing the medical use of cannabis in those states.

B. Unless the federal government has sought to preempt the field, which it has not done with drug laws, the Supremacy Clause does not prohibit states from enacting laws in the same area which differ in their approach.

C. There is a constitutional right of privacy and substantive due process right in the medical use of cannabis when the decision is made under state law between a doctor and a chronically or terminally ill patient seeking to preserve a tolerable quality of life, under three separate but interrelated constitutional theories:

1. The decision to use medical cannabis can be the difference between a horrible existence or a minimal quality of life as death approaches. When sentient life becomes almost unbearable, anything that improves that life takes on a constitutional dimension. People have the right to define their own concept of existence. That right is the essence of the natural law upon which the Declaration of Independence and its "pursuit of happiness" and due process of law are founded. *Cruzan* holds that due process includes protection of the quality of life, and that applies here.

2. Implicit in the Bill of Rights is the "right to be let alone" by government. In *Winston v. Lee*, this Court recognized that some parts of the "right to be let alone" are more important than the government's interest in doing what it wants. The personal medical decision to use medical cannabis to alleviate suffering is such a right.

3. The right to medical use of cannabis is also protected by substantive due process because both pain relief and cannabis are recognized in our "history, legal traditions, and practices." The right to substantive due process must insure that chronically and terminally ill Americans should have the right to doctor-approved medical use of

cannabis if it alleviates their debilitating pain and suffering or improves their quality of life in the days before their death.

III. The claim that federal drug law enforcement is harmed by medical use is untenable. Whatever one's stance on the "war on drugs," the prosecution of drug offenses by the federal government will go on unabated even if state chartered cannabis buyers' clubs are permitted to operate. The class of potential offenders that the federal government has selected are not drug abusers, but patients with doctor's recommendations for treatment. The law enforcement and judicial machinery otherwise never would waste resources on such offenders. This issue involves no meaningful interest of the federal government, other than an opportunity to make a symbolic political statement in the "war on drugs." Casualties in the "war on drugs" should not be the chronically and terminally ill who are aided by medical use of cannabis.

ARGUMENT

I. Introduction

A. What this case is and what it is not

This case is not about a backdoor effort to get "stoned," as petitioner's *amici* so cavalierly assert.[6] The chronically sick and dying who, in private consultation with doctors, have determined they have no other recourse other than medical use of cannabis, take serious issue with the *amici*'s attack on their medicine. The respondents assert the fundamental right of their patients

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[6] Brief of Institute on Global Drug Policy of the Drug Free America Foundation, *et al.*, as *Amici Curiae*, 8-9; Brief of Family Research Council as *Amicus Curiae*, 26-28. *See* note 2, *supra*.

to enhance the quality of whatever is left of their lives, when other treatment and medication have failed to relieve suffering. This case also concerns the fundamental right to exercise legislative power as reserved by the Ninth and Tenth Amendments, to the people of nine states. Finally, this case presents an exercise of law enforcement authority in a limited area by the federal government where it lacks constitutional power to act.

Popularly enacted legislation permitting compassionate medical use of cannabis is an assertion of a fundamental right by the people and the states. Those state laws recognize a right for patients who have lost any real quality of life from chronic or terminal illness to be free from unnecessary pain and suffering. Enabling patients whose medical conditions deny them a quality of life to use medical cannabis with their doctor's oversight is a matter fully reserved to the people and the states under the Ninth and Tenth Amendments that the federal government must respect. The federal government has no power to legislate in this area under either the commerce clause or "necessary and proper" clause of Art. I, § 8 of the Constitution.[7]

This case involves numerous fundamental interests at risk in the attempt by federal law to prohibit what nine states have allowed. This exercise of rights by the people and the states to legislate in matters of personal human dignity is protected from federal abrogation under our fundamental concept of ordered liberty and federalism.

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[7] "The government . . . can claim no powers which are not granted to it by the constitution, and the powers actually granted, must be such as are expressly given, or given by necessary implication." *Martin v. Hunter's Lessee*, 14 U.S. (1 Wheat.) 304, 326 (1818).

The people and states are unilaterally entitled to legislate what means they believe better serve their own defined goals, where there is no compelling conflicting federal interest, and where they have made a personal medical choice after consultation with a doctor. This conflict implicates multiple individual liberties intertwined under our Constitution: The right of the "pursuit of happiness" and liberty by the chronically and terminally ill; the right of people "to be let alone" by their government in these personal decisions; and substantive due process, particularly when there is no serious federal interest in prohibiting the conduct at issue.

B. The efficacy and public acceptance of the medical use of cannabis

Petitioner's *amici* trivialize the irrefutable facts of this case that many sick people simply are not helped by conventional drug therapy for serious medical conditions.[8] Petitioners' *amici* ignore the 5,000 years of recognized medical use of cannabis,[9] including a wealth of

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[8] *Amici Curiae* Brief of Institute on Global Drug Policy of the Drug Free America Foundation, *et al.*, 8-9.

[9] LESTER GRINSPOON, M.D. & JAMES B. BAKALAR, MARIHUANA: THE FORBIDDEN MEDICINE 3-5 (Rev.ed. 1997) ("The first evidence of the medicinal use of cannabis is an herbal published during the reign of Chinese Emperor Chen Nung five thousand years ago. [¶] It was listed in the United States Dispensatory in 1854. . . . Commercial cannabis preparation could be bought in drug stores. . . . [¶] Meanwhile, reports on cannabis accumulated in the medical literature."). *See Regina v. Parker, infra*, ¶ 123:

> Like many other herbs, marihuana has been used in Asian and Middle Eastern countries for at least 2600 years for medicinal purposes. It first appeared in Western medicine in 60 A.D. in the Herbal (i.e.

modern articles on the utility of the medicinal use of cannabis, and the history of cannabis use in the United States beginning before our colonization.[10] The most recent books citing published findings are: LESTER GRINSPOON, M.D. & JAMES B. BAKALAR, MARIHUANA: THE FORBIDDEN MEDICINE (Rev.ed. 1997) and NATIONAL ACADEMY OF SCIENCES'S INSTITUTE OF MEDICINE, MARIJUANA AND MEDICINE:

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pharmacopoeia) of Dioscorides and was listed in subsequent herbals or pharmacopoeia since that time. Marihuana was widely used for a variety of ailments, including muscle spasms, in the nineteenth century. In the 1930's, the advent of synthetic drugs led to the abandonment of many ancient herbal remedies including marihuana, although an extract of cannabis and a tincture of cannabis remained in the British Pharmaceutical Codex of 1949.

[10] GRINSPOON & BAKALAR, *supra*, Ch. 1.

Some of our founding fathers were hemp growers. Bergoffen & Clark, *Hemp as an Alternative to Wood Fiber in Oregon*, 11 J.ENVTL.L. & LITIG. 119, 120-21 (1996):

> In North America, hemp was widely used before European settlement, contrary to popular views. . . . John De Verrazano discovered it growing wild in Virginia in 1524. It is also well established that marijuana has been used for both religious and recreational purposes for thousands of years.
>
> . . . In Virginia in the 1760s, a bounty of "four shillings for every gross hundred of hemp" was to be paid to farmers. Most famous of these Virginia hemp farmers were George Washington and Thomas Jefferson; Jefferson considered hemp so important that he even arranged to smuggle Chinese hemp seeds back to the United States because of their superior qualities. Another forefather, Benjamin Franklin, founded one of America's first paper mills, which used hemp as its fibersource.

ASSESSING THE SCIENCE BASE (1999).[11] Even the DEA's ALJ recognized that the case for the medical use of cannabis presented by NORML was *never refuted* by the agency. The DEA would not hear of it, however, and refused to adopt the ALJ's recommendation despite the uncontradicted evidence. (*See* notes 3-5, *supra.*)

Petitioner's *amici* also overlook the sheer numbers of ordinary people who recognize that there should be compassionate use of cannabis. (Appendix A)[12] Many influential American and other medical organizations and health care providers recognize that there is a bona fide need for the medical use of cannabis when a doctor and patient decide it is necessary. (Appendices B & C)

II. The medical use of cannabis is an individual right that should be recognized by this Court in states where the people have enacted laws permitting it

This case presents the recognition of important legal doctrines at the heart of our form of constitutional government: individual liberty and the powers reserved to the people and the states. As a matter of individual liberty, it should be beyond the power of the federal government to regulate the medicinal use of cannabis when the voters or legislatures of states decide it should be legalized for medical use. Nine states with 20.51% of

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[11] The latter is online at http://bob.nap.edu/books/0309071550.html/.

[12] The nine states having legalized medical use of cannabis comprise approximately 20.51% of the U.S. population (based on 1999 estimates: approximately 55,919,000 of 272,690,000; the 2000 census data will not be available until the Spring of 2001) (http://quickfacts.census.gov/qfd/index.html).

the population have approved of the medical use of cannabis since 1996 (*see* note 12, *supra*): Eight by initiative[13] and one by the legislature. The public and medical organizations strongly support medical cannabis use for those who would be aided by it. (Appendices A-C)

It is only natural, then, that the proponents of the medical use of cannabis go directly to the people when a state legislature fails to act. It is, no doubt, a natural right.

A. The power of the people to initiate legislation reserved by the Ninth and Tenth Amendments

The power of initiative and referendum appears in about half of the state constitutions,[14] as it does in California. Cal. Const., Art. 4, § 1. This quintessential reservation of political and legislative power is expressly reserved to the people and the States under the Ninth and Tenth Amendments.[15] In addition, the initiative power is clothed with full First Amendment protection as "core political speech" and a method of petitioning government for redress of grievances. *See Meyer v. Grant*, 486 U.S. 414, 421-22 (1988):

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[13] The District of Columbia also approved of it, but Congress nullified it.

Oregon's Department of Human Services today reports 1,700 registered patients and 519 physicians have provided documentation for their patients to register. There were 900 in the program on the first anniversary, May 1, 2000. Kelly Paige, Medical Marijuana Program Manager, Oregon Health Division, Department of Human Services (Feb. 2001). The program's website is: www.ohd.hr.state.or.us/hclc/mm/.

[14] *Lucas v. Forty-Fourth General Assembly*, 377 U.S. 713, 734 (1964).

[15] *Cammarano v. United States*, 358 U.S. 498, 506 (1959) (state constitutions "explicitly recognize that in providing for initiatives they are vesting legislative power in the people").

> The circulation of an initiative petition of necessity involves both the expression of a desire for political change and a discussion of the merits of the proposed change. [A] petition circulator . . . will at least have to persuade them that the matter is one deserving of the public scrutiny and debate that would attend its consideration by the whole electorate. This will in almost every case involve an explanation of the nature of the proposal and why its advocates support it. Thus, the circulation of a petition involves the type of interactive communication concerning political change that is appropriately described as "core political speech."

B. Federal deference to state law on the medical use of cannabis, and the inapplicability of the Supremacy Clause

Once the voters of a state have adopted an initiative or a state legislature has enacted a statute protecting the medical use of cannabis, the people of that state have compellingly expressed their public policy, even if that public policy differs from that of the federal government. Federalism mandates that state public policy is entitled to presumptive deference. State legislation expresses its public policy; *Schall v. Martin*, 467 U.S. 253, 281 (1984); especially legislation adopted directly by the people.[16]

The Supremacy Clause, U.S. Const., Art. IV, cl. 2, provides the federal government no support in its attempt to nullify this state law because Congress has not even remotely attempted to preempt every part of the

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[16] Also, "state legislatures are *not* subject to federal direction. *New York v. United States*, 505 U.S. 144 (1992)." *Prinz v. United States*, 521 U.S. 898, 912 (1997) (emphasis in original).

field of criminalizing drug crimes. Indeed, every state has laws against the illegal use, manufacture, and distribution of controlled substances. And, the federal government could not preempt drug regulation even if it wished, because there is no general federal police power, a power singularly reserved to the states. *Lopez v. United States*, 514 U.S. 549, 560 n.3 (1995). Indeed, *Lopez* portended the conflict here: "When Congress criminalizes conduct already denounced as criminal by the States, it effects ' "a change in the sensitive relation between federal and state criminal jurisdiction." ' " *Id.* (quoting *United States v. Bass*, 404 U.S. 336, 349 (1971)).

Federal and state drug laws have co-existed for more than half a century, and state laws recognizing medical use of cannabis manifestly do not " 'stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Development Comm.*, 461 U.S. 190, 203-04 (1983) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

As in *Lopez*, Congress cannot remain in denial of reality and cannot declare night to be day and simply expect this Court to rubber stamp that conclusion. *Lopez*, 514 U.S. at 566-67. *Kelly v. Washington ex rel. Foss Co.*, 302 U.S. 1, 9-10 (1937), answers this question for us:

> Under our constitutional system, there necessarily remains to the States, until Congress acts, a wide range for the permissible exercise of power appropriate to their territorial jurisdiction although interstate commerce may be affected. . . . States are thus enabled to deal with local exigencies and to exert in the absence of

> conflict with federal legislation an essential protective power. And when Congress does exercise its paramount authority, it is obvious that Congress may determine how far its regulation shall go. There is no constitutional rule which compels Congress to occupy the whole field. Congress may circumscribe its regulation and occupy only a limited field. When it does so, state regulation outside that limited field and otherwise admissible is not forbidden or displaced. The principle is thoroughly established that the exercise by the State of its police power, which would be valid if not superseded by federal action, is superseded only where the repugnance or conflict is so "direct and positive" that the two acts cannot "be reconciled or consistently stand together." (citations omitted)

Thus, unless Congress dictates that the states may not regulate drug crimes, something it will never do, the federal government cannot claim preemption.

C. The right of liberty, privacy, and substantive due process in medical use of cannabis

There is a constitutional right of privacy and a substantive due process right in the medical use of cannabis when that decision is made under state law between a doctor and a chronically or terminally ill patient seeking to preserve a tolerable quality of life. This right is more significant when patients seek to preserve some semblance of human dignity and freedom from the ravages of disease in their final days. This principle is founded on three interrelated constitutional theories:

1. Rights to the dignity of life, individual liberty and autonomy, and the "pursuit of happiness"

For some patients, the decision to use medical cannabis can be the difference between a horrible existence or a minimal quality of life as death approaches. When a state has permitted the use of medical cannabis for these people, after conventional medication has failed or forced them to suffer intolerable side effects, their very ability to define their life is at stake. When the quality of life becomes almost unbearable, anything that improves that quality of life has a constitutional dimension. "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State." *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 850-51 (1992).

Indeed, "defin[ing] one's own concept of existence" is the essence of the natural law expressed in ¶ 2 of the Declaration of Independence: "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness." As the Court stated in *Board of Regents v. Roth,* 408 U.S. 564, 572 (1972), the Court has not attempted to define with exactness the liberty guaranteed by due process, because, "[i]n a Constitution for a free people, there can be no doubt that the meaning of 'liberty' must be broad indeed."

> Our Constitution is born of the proposition that all legitimate governments must secure the equal right of every person to "Life, Liberty, and the pursuit of Happiness." In the ordinary case

> we quite naturally assume that these three ends are compatible, mutually enhancing, and perhaps even coincident.
>
> . . . Together, these considerations suggest that Nancy Cruzan's liberty to be free from medical treatment must be understood in light of the facts and circumstances particular to her.

Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261, 331 (1990) (STEVENS, J., dissenting) (footnote omitted)

A state has an "unqualified interest in the preservation of human life." *Cruzan*, 497 U.S. at 282. Because of that interest, states sometimes seek the preservation of life notwithstanding the utter lack of quality of that life. Thus, Nancy Cruzan's family had to fight the State of Missouri which wanted to keep her alive by state mandated medical intervention. The federal government tells us that patients who want to preserve their own life, who are struggling to stay alive despite painful or debilitating side effects of modern medicine, have no right to preserve any semblance of dignity of their waning life by medical procedures approved by the voters of their state. Is it not ironic that a prison inmate can be judicially forced to be medicated to have a quality of life on death row or in prison or for the preservation of his life, even to later execute him?[17] Yet here, the government denies a comparable right to the chronically or terminally ill

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[17] A state may force inmates to take anti-psychotic medication to restore sanity when they are so disturbed that they have no quality of life and are a danger to themselves or others; *Washington v. Harper*, 494 U.S. 210 (1990); even if this medical intervention is forced on them, would make the inmates competent, and thus enable the state to execute them. *Singleton v. Norris*, 338 Ark. 135, 992 S.W.2d 768 (1999), *cert. den.* 528 U.S. 1084 (2000).

patient who could benefit from the medical use of cannabis. This judicial distinction, to heal prisoners but harm terminal patients, is irrational and contrary to any concept of ordered liberty in a free nation.

If a state has such an "unqualified interest in the preservation of life," it must of necessity also have an interest in the quality of the life it preserves as the end approaches. In some situations, particularly the AIDS wasting syndrome, the medical use of cannabis usually provides the *only means to sustain life*. If so, then there should be a constitutional right to use it.

2. The right to privacy in "the right to be let alone" by government

There is a basic right to privacy in this nation, "the right to be let alone," and it runs throughout the law of individual liberty. Whatever its source, be it in the common law,[18]

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[18] *See Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891), where a railroad sought a physical examination of an injured passenger. This Court affirmed the lower court's refusal to permit the examination of her body so the railroad could separately evaluate the seriousness of her injury:

> No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law. As well said by Judge Cooley: "The right to one's person may be said to be a right of complete immunity; to be let alone." Cooley, Torts, 29.

See Poe v. Ullman, 367 U.S. 497, 521 & n.12 (1961) (DOUGLAS, J., dissenting) ("The notion of privacy is not drawn from the blue. [n12: The right 'to be let alone' had many common-law overtones.] It emanates from the totality of the constitutional

the law of torts,[19] the Ninth Amendment, one of those "penumbra" rights within the Bill of Rights as a whole,[20] or whether it is a liberty interest under the due process clauses of the Fifth and Fourteenth Amendments,[21] government must recognize that certain rights reserved to the people and states are beyond its reach.

The phrase was truly memorialized in Justice BRANDEIS's famous dissent 73 years ago in *Olmstead v. United States*, 277 U.S. 438, 478 (1928):

> The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found

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scheme under which we live.") & 543 (HARLAN, J., dissenting) (in addition, it protects against "arbitrary impositions and purposeless restraints" by government (quoting *Hurtado v. California*, 110 U.S. 516, 632 (1884)).

[19] *See generally* Warren & Brandeis, *The Right to Privacy*, 4 HARV.L.REV. 193 (1890); Prosser, *Privacy*, 48 CALIF.L.REV. 391 (1960); Griswold, *The Right to be Let Alone*, 55 NW.U.L.REV. 216 (1960).

[20] *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965) (there is a penumbra of privacy rights, "zones of privacy," in the First, Third, Fourth, and Ninth Amendments).

[21] *Id.*, 381 U.S. at 493 (GOLDBERG, J., concurring) (due process and Ninth Amendment), 500 (HARLAN, J., concurring) (basic to concept of "ordered liberty" for due process) & 507 (WHITE, J., concurring) (due process violated because government cannot pass such a law); *Cruzan*, 497 U.S. at 279 n.7 (liberty interest under the Fourteenth Amendment in refusing medical treatment with a "right to die").

> in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone – the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the Government upon the privacy of the individual, whatever the means employed, must be deemed a violation of the Fourth Amendment.[22]

While the "right to be let alone" originally emerged into this Court's cases in a dissent, the existence of a constitutional right "to be let alone" is now well accepted. The Court has repeatedly cited *Olmstead* and considered "the right to be let alone" as a part, not only of the Fourth Amendment,[23] but also the First,[24] Fifth,[25] and Fourteenth[26] Amendments.

The "right to be let alone" has been found to outweigh even one of the weightiest of governmental interests: The interest in procuring evidence to prosecute a violent crime. In *Winston v. Lee*, 470 U.S. 753, 765-66 (1985), the Court denied the government the ability to obtain evidence by forced major surgery on the body of

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[22] Justice BRANDEIS also said, *id.* at 479: "The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."

[23] *California Bankers Assn. v. Shultz*, 416 U.S. 21, 65 (1974); *Winston v. Lee*, 470 U.S. 753, 758-59 (1985). *See Katz v. United States*, 389 U.S. 347, 350-51 & n.6 (1967).

[24] *Stanley v. Georgia*, 394 U.S. 557, 564 (1969); *Rowan v. U.S. Post Office Dept.*, 397 U.S. 728, 736 (1970).

[25] *Tehan v. United States ex rel. Shott*, 382 U.S. 406, 416 (1966). *See United States v. Morton Salt Co.*, 338 U.S. 632, 651-52 (1950).

[26] *Eisenstadt v. Baird*, 405 U.S. 438, 453-54 n.10 (1972).

the accused to remove a bullet, even where the search would certainly produce evidence of a violent crime:

> The Fourth Amendment protects "expectations of privacy," see *Katz v. United States*, 389 U.S. 347 (1967) – the individual's legitimate expectations that in certain places and at certain times he has "the right to be let alone – the most comprehensive of rights and the right most valued by civilized men." *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (BRANDEIS, J., dissenting). Putting to one side the procedural protections of the warrant requirement, the Fourth Amendment generally protects the "security" of "persons, houses, papers, and effects" against official intrusions up to the point where the community's need for evidence surmounts a specified standard, ordinarily "probable cause." Beyond this point, it is ordinarily justifiable for the community to demand that the individual give up some part of his interest in privacy and security to advance the community's vital interests in law enforcement; such a search is generally "reasonable" in the Amendment's terms.

But, the Court held that this compelled surgical intrusion for evidence implicated expectations of privacy and personal security to such a degree that the intrusion was constitutionally unreasonable under the Fourth Amendment even though it certainly would produce evidence of a violent crime. *Id.* at 758-59. The government's normally compelling need to obtain vital evidence to enforce the criminal law and prosecute a violent criminal constitutionally had to give way to the personal dignity of the individual because the search was "unreasonable" under the Fourth Amendment.

That rationale applies with equal force here: No matter what the governmental interest in prosecuting drug

crimes, the personal and fundamental interest in preserving the dignity of life should weigh more heavily, particularly when a state has declared its public policy that its citizens are entitled to the benefit of the medical use of cannabis.

3. Substantive due process: "history, legal traditions, and practices"

Analogous to the above two standards and using similar language, but still clearly a standard of its own, is the right to substantive due process under the Fifth and Fourteenth Amendments. If the right to substantive due process means anything, it should mean that chronically and terminally ill Americans should have the right to medical use of cannabis if it alleviates suffering from their serious medical condition and thereby gives them some quality of life in the days before their death. This Court has already recognized a substantive due process right to be free from pain and suffering in *Cruzan*, involving a woman who was in a persistent vegetative state whose family wanted to have a feeding tube withdrawn so she could die and be allowed to be free of her misery. *A fortiori*, it naturally flows from that case that there also is a parallel right patients in chronic pain or the terminally ill have to alleviate their pain and suffering *when they want to live*. Nancy Cruzan had a right to stop being force fed and to die to alleviate her pain and suffering that was caused merely by her being kept alive in that condition. For patients with their doctors' approval, who want to go on living but without their pain and suffering, patients must also have an "unqualified interest in the preservation of human life." One should flow from the other.

After *Cruzan*, the Court held in *Washington v. Glucksberg*, 521 U.S. 702 (1997), that there was no due process right to assisted suicide. The Court stated its approach to due process issues; *id.* at 710:

> We begin, as we do in all due-process cases, by examining our Nation's history, legal traditions, and practices. *See, e.g., Casey*, 505 U.S. at 849-850; *Cruzan*, 497 U.S. at 269-279; *Moore v. East Cleveland*, 431 U.S. 494, 503 (1977) (plurality opinion) (noting importance of 'careful "respect for the teachings of history" ').[27]

This substantive due process analysis derives from Justice HARLAN's dissent in *Poe v. Ullman*, 367 U.S. 497, 542-43 (1961), elucidating the true meaning of "the full scope of liberty" under due process:

> It is this outlook which has led the Court continuingly to perceive distinctions in the imperative character of Constitutional provisions, since that character must be discerned from a particular provision's larger context. And inasmuch as this context is one not of words, but of history and purposes, the full scope of the liberty guaranteed by the Due Process Clause cannot be found in or limited by the precise terms of the specific guarantees elsewhere provided in the Constitution. This "liberty" is not a series of isolated points pricked out in terms of the taking of property; the freedom of speech, press, and religion; the right to keep and bear arms; the freedom from unreasonable searches

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[27] *See Roe v. Wade*, 410 U.S. 113, 140 (1973) (from the founding of the nation and throughout the Nineteenth Century, "a woman enjoyed a substantially broader right to terminate a pregnancy"; thus, history supported the finding of an individual right to terminate a pregnancy).

> and seizures; and so on. It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment. . . . (citations omitted)

Justice HARLAN's opinion in *Poe* is recognized as the source of modern individual judicial review of substantive due process claims.[28]

Our "history, legal traditions, and practices" unequivocally tell us that the individual is more important than the government and that government interference with a person's autonomy must be based on

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[28] *Washington v. Glucksberg, supra,* at 766 n.4 (SOUTER, J., dissenting):

> The status of the Harlan dissent in *Poe v. Ullman,* . . . , is shown by the Court's adoption of its result in *Griswold v. Connecticut,* . . . , and by the Court's acknowledgment of its status and adoption of its reasoning in *Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833, 848-849 (1992). See also *Youngberg v. Romeo,* 457 U.S. 307, 320 (1982) (citing Justice HARLAN's *Poe* dissent as authority for the requirement that this Court balance "the liberty of the individual" and "the demands of an organized society"); *Roberts v. United States Jaycees,* 468 U.S. 609, 619 (1984); *Moore v. East Cleveland,* 431 U.S. 494, 500-506, and n.12 (1977) (plurality opinion) (opinion for four Justices treating Justice HARLAN's *Poe* dissent as a central explication of the methodology of judicial review under the Due Process Clause).

extremely important societal interests.[29] In some cases, an individual's right to personal autonomy can outweigh even the undeniably powerful governmental interest in prosecuting violent crime, as in *Winston v. Lee*. We must never forget that our government exists to serve its citizens; the citizens do not exist to serve the government.[30] Moreover, medical use of cannabis is a part of our nation's history and the history of civilization for the last 5,000 years. State authorized medical use of cannabis for patients with a dire need thus clearly qualifies for recognition under substantive due process.

4. The Canadian experience

Canada's Charter of Rights was adopted less than two decades ago, and it closely parallels our Bill of Rights; so much, indeed, that the Canadian courts apply

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[29] *United States v. Oakland Cannabis Buyers' Coop.*, 121 S.Ct. 21 (2000) (STEVENS, J., dissenting from grant of stay):

> Because the applicant in this case has failed to demonstrate that the denial of necessary medicine to seriously ill and dying patients will advance the public interest or that the failure to enjoin the distribution of such medicine will impair the orderly enforcement of federal criminal statutes, whereas respondents have demonstrated that the entry of a stay will cause them irreparable harm, I am persuaded that a fair assessment of that balance favors a denial of the extraordinary relief that the government seeks. I respectfully dissent.

[30] *See* the Declaration of Independence ¶s 3 & 28. *See also McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 405 (1819) ("The government . . . is emphatically, and truly, a government of the people. In form and in substance it emanates from them. Its powers are granted by them, and are to be exercised directly on them, and for their benefit.").

American case law as an aid in interpreting their Charter.[31] Similarly, because of our geographic proximity and open border, political alliances, and similar adversary system with the same common law origin, this Court has looked to Canadian law and experience as an aid in interpreting our Bill of Rights.[32]

Section 7 of the Canadian Charter of Rights and Freedoms is their version of our Due Process Clause, and it provides that "[e]veryone has the right to life, liberty and security of the person and the right not to be deprived of those rights except in accordance with the principles of fundamental justice." Less than a year ago, the Ontario Court of Appeals found a fundamental right in the medical use of cannabis for the chronically ill, just as is asserted here. The Canadian government is attempting to implement medical use for distribution through its national health care system.[33] Thus, there is a right to the needful medical use of cannabis, notwithstanding that possession and delivery of cannabis otherwise remains a

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[31] *Regina v. Carter*, 2 C.R.R. 280, 144 D.L.R.(3d) 301, 304-05 (Ont.Ct.App. 1982) (American decisions may be persuasive). For example, running obvious queries ("U.S.," "F.3d," "Fourth Amendment") through their case data base on Lexis® will produce nearly 1,000 hits.

[32] *See, e.g., Nixon v. Shrink Missouri Gov't PAC*, 528 U.S. 377, 403 (2000) (BREYER and GINSBURG, JJ, concurring); *Washington v. Glucksberg, supra*, at 713 (noting that Canadian courts had recently rejected a right to assisted suicide); *McIntyre v. Ohio Election Comm.*, 514 U.S. 334, 381 (1995) (SCALIA, J., dissenting).

[33] Harris, "Rock feels road to the PMO begins as a good health minister," *The Ottawa Citizen* A13, ¶ 14 (Jan. 28, 2001) (describing how the new health minister "has managed to get a formal medical-marijuana policy in place in Canada, including the identification of a supplier for the otherwise illegal drug.").

crime in Canada. *Regina v. Parker,* 75 C.R.R.(2d) 233, 2000 C.R.R.Lexis 96 (Ont.Ct.App. 2000) (right to use cannabis to control epilepsy; Marinol® was not helpful to Parker but cannabis was; medical necessity defense sustained as a fundamental right); *Regina v. Clay,* 75 C.R.R.(2d) 210, 2000 C.R.R.Lexis 97 (Ont.Ct.App. 2000) (no fundamental right to recreational possession of marijuana notwithstanding *Parker*'s recognition of a medical necessity right; both decided same day).

Parker was thus held to have a complete defense to criminal prosecution for his possession and cultivation of cannabis for his personal medical use. The Canadian court's analysis in *Parker* closely parallels this Court's own due process analysis:

> [¶ 96] . . . "[s]ection 7 is also implicated when the state restricts individuals' security of the person by interfering with, or removing from them, control over their physical or mental integrity". There is no question, then, that personal autonomy, at least with respect to the right to make choices concerning one's own body, control over one's physical and psychological integrity, and basic human dignity are encompassed within security of the person, at least to the extent of freedom from criminal prohibitions which interfere with these. . . .
>
> [¶ 102] In my view, Parker has also established that the marihuana prohibition infringed the second aspect of liberty that I have identified – the right to make decisions that are of fundamental personal importance. As I have stated, the choice of medication to alleviate the effects of an illness with life-threatening consequences is a decision of fundamental personal importance. In my view, it ranks with the right to choose whether to take mind-altering psycho-

> tropic drugs for treatment of mental illness, a right . . . ranked as "fundamental and deserving of the highest order of protection" in *Fleming v. Reid* (1991). . . .

The Ontario court's approach underscores the utter implausibility of the government's justification for bringing this case: The Canadian government has no trouble prosecuting recreational marijuana cases despite a fundamental right to medical use, but the United States government believes otherwise. As respondents have pointed out, despite California's Compassionate Use Act of 1996 and that state's decriminalization of small personal use amounts of cannabis, the number of marijuana arrests in California has increased. The law enforcement interest, if it exists at all (and, in light of *Winston v. Lee*, we do not agree that it does), is not remotely or legitimately limited or harmed by medical use legislation. They can co-exist.

D. Civilized notions of personal liberty require this Court to recognize a constitutional right to state chartered doctor-supervised treatment that is superior to any interest in federal prohibition

Fundamental notions of personal liberty under our scheme of constitutional government and federalism require this Court to recognize that, when a state explicitly permits its citizens medical use of cannabis when doctor and patient agree, there is a fundamental constitutional right to the use of medical cannabis, free from unreasonable federal interference.

III. The claim that federal drug law enforcement is harmed by the Compassionate Use Act of 1996 is untenable

Proposition 215, the California Compassionate Use Act of 1996, has had no material effect on the federal government's law enforcement machinery. Until this case, the federal government never wasted the time and resources of the DEA and the U.S. Attorney's Offices on such small cases. This case was brought merely to intimidate California voters by showing that the federal government is fighting the "war on drugs." The fact *no one* has been federally prosecuted for distribution from a buyers' club created under Proposition 215 is truly telling. The federal government's resources are better spent on other aspects of the "war on drugs" where it can plausibly, if not credibly, claim that it really believes marijuana is a danger to society. The primary governmental entities with law enforcement jurisdiction over respondents, the State of California, Alameda County, and the City of Oakland have found respondents' conduct entirely legal. Indeed, the City of Oakland has designated the Oakland Cannabis Buyers' Club a health care provider under Proposition 215.

The state and federal government will continue to fight the "war on drugs," notwithstanding Proposition 215 and local decriminalization of possession of small amounts, notwithstanding the drug war's apparently counterproductive impact on the availability of illegal drugs and the harm they cause. The federal spending on the war on drugs has increased seven-fold in 15 years,[34]

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[34] The Office of National Drug Control Policy FY 1985 budget was $2.7 billion. The FY 2001 proposed budget is $19.2

and the number of people incarcerated for drug crimes has grown 1,000% in twenty years.[35] The war on drugs, however, has done absolutely nothing to prevent teenagers from experimenting with cannabis.[36] The government's ability to prosecute those who import, grow, and deal marijuana for profit has been unimpeded by Proposition 215. Marijuana arrests have risen in California since Proposition 215 and the decriminalization of possession of small amounts, while bona fide patients have gained security from the publicly regulated access to the medicine they need. *See* J.A. 158-59. Most interestingly, and contrary to what is claimed here, the federal government has not claimed there is any interference with federal law enforcement interests in the ten states (including California) that decriminalize small amounts of cannabis. Why the distinction? It is a tacit admission, and the government's argument must fail.

The federal government virtually *never* prosecutes cases involving individual users of small amounts of marijuana. The states usually do because it falls within

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billion. THE NATIONAL DRUG CONTROL STATEGY: FY 2001, BUDGET SUMMARY 2000 ANNUAL REPORT, Table 3 tp://www.whitehousedrugpolicy.gov/policy/budget00/exec___summ.html#table3.

[35] There are now more than 450,000 drug offenders behind bars, a total nearly equal to the entire U.S. prison population of 1980. SCHIRALDI & ZIEDENBERG, POOR PRESCRIPTION: THE COST OF IMPRISONING DRUG OFFENDERS IN THE UNITED STATES, Justice Policy Institute (2000).

[36] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, MONITORING THE FUTURE NATIONAL RESULTS ON ADOLESCENTS DRUG USE: OVERVIEW OF KEY FINDINGS, Table 9: Long-Term Trends in Perceived Availability of Drugs by Twelfth Graders: Marijuana 1975-2000 (2001).

their police power and not the federal government's. This fact only adds to the conclusion that there is no meaningful federal interest involved in Proposition 215. Casualties in the "war on drugs" should not be the chronically and terminally ill who are aided by medical use of cannabis.

CONCLUSION

If our Constitution means anything, it should mean that "the war on drugs" cannot be made to be a war on the quality of life of the chronically or terminally ill. Sadly, our government believes in a constitutional regime that enables it to enforce its policies which enhance patient pain contrary to state law. This Court must reject any such view of the constitution that interferes with the rights of both citizens and the states to enact laws for their common good where there is no federal interest.

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX A

POLLS DEMONSTRATING PUBLIC SUPPORT FOR MEDICAL USE OF CANNABIS 1995-2000

UNITED STATES:

Denver Post/9 News/KOA News Radio, October 2000

* 67 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: *Denver Post*/9 News/KOA News Radio poll, as reported by *The Denver Post*, October 5, 2000 (Sample size: not available).

Denver Rocky Mountain News/News 4, September 2000

* 71 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: *Denver Rocky Mountain News*/News 4 poll, as reported by *The Denver Rocky Mountain News*, September 17, 2000 (Sample size: not available).

Las Vegas Review Journal, September 2000

* 63 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: Mason-Dixon Research Poll, as conducted for and reported by the *Las Vegas Review Journal*, September 9-12, 2000 (Sample size: 627).

Bangor Daily News/WCSH 6/WLBZ 2, October 1999

* 61 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: Survey USA poll, as reported by the *Bangor Daily News*, October 28, 1999. (Sample size: 500).

CNN Interactive Poll, April 1999

* 96 percent of respondents said they "support the use of marijuana for medicinal purposes."
* 89 percent of respondents said they did not "think legalizing medical marijuana would open the doors to the legalization of other illicit drugs."
* Source: CNN Interactive Ongoing Quick Poll: http://www cgi.cnn.com/cgibin/poll/npoll.pl?question =0&subject=9702%2Fmarijuana (Sample size: 31,294).

Prevention Magazine Internet Poll, April 1999

* 89 percent of respondents said they support allowing doctors to "prescribe marijuana as a medical treatment."
* Source: *Prevention Magazine's* "Healthy Ideas" weekly poll: http://www.healthyideas.com/poll/971003/ (Sample size: 637).

Gallup Poll, March 1999

* 73 percent of respondents said they "would vote for making marijuana legally available for doctors to prescribe."
* Source: Gallup Poll News Service, conducted March 21, 1999, as reported in the National Journal, April 10, 1999 (Sample size: not available).

Chicago Sun-Times Poll, March 1999

* 90 percent of respondents said the federal government should approve the use of marijuana for medical purposes.
* Source: Morningline telephone poll, as conducted for and reported by the *Chicago Sun-Times*, March 18, 1999 (Sample size: not available).

Mason-Dixon Research Poll, March 1999

* 64 percent of respondents favored "protecting patients who use medical marijuana from civil or criminal penalties."

* Source: Mason-Dixon Research Poll of regional Minnesota state voters, released March 15, 1999 (Sample size: 800).

Harris/Excite Poll, March 1999

* 82 percent of respondents said doctors "should be able to prescribe marijuana."
* Source: Harris/Excite Daily Internet Poll for March 18, 1999: http://nt.excite.com/poll/history.dcg?show=day&id=990318 (Sample size: 20,763).

Hawaii Voter Poll, October 1998

* 63 percent of respondents said they "support the use of marijuana for medicinal purposes."
* Source: Hawaii Voter Poll conducted by Fairbanks, Maslin, Maulin & Associates from September 30-October 4, 1998, as reported by the *Honolulu Advertiser*, October 27, 1998 (Sample size: 400).

JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (JAMA) Poll, March 1998

* 60 percent of respondents supported allowing physicians to prescribe medical marijuana.
* Source: JAMA poll, conducted by Harvard School of Public Health, as reported by Reuters News Service, March 17, 1998 (Sample size: not available).

The New Yorker Poll, January 1998

* 85 percent of respondents supported "permitting doctors to prescribe marijuana."
* Source: The Narcissus Survey, conducted by Penn, Schoen & Berland for *The New Yorker Magazine*, as reported January 5, 1998 (Sample size: 1,400).

Luntz Research National Poll, November 1997

* 62 percent of respondents favored legalizing marijuana "strictly for medical use."

* Source: "Digital Citizen Survey," conducted by The Luntz Research Companies for Merrill Lynch and *Wired Magazine:* September 7-21, 1997 (Sample size: 1,444).

Florida Voter Poll, September 1997

* 63 percent of respondents favored approving an amendment to the Florida Constitution legalizing "medicinal" marijuana.
* Source: Florida Statewide Voter Poll, as reported by *The Miami Herald,* September 23, 1997 (Sample size: 400).

CBS News Poll, June 1997

* 66 percent of Independent respondents said that "doctors should be allowed to prescribe small amounts of marijuana for patients suffering serious illnesses."
* 64 percent of Democrat respondents said that "doctors should be allowed to prescribe small amounts of marijuana for patients suffering serious illnesses."
* 57 percent of Republican respondents said that "doctors should be allowed to prescribe small amounts of marijuana for patients suffering serious illnesses."
* Source: CBS News national telephone poll, as reported by *The New York Times,* June 15, 1997 (Sample size: not available).

ABC News/Discovery News Poll, May 1997

* 69 percent of respondents favored "legalizing [the] medical use of marijuana."
* Source: ABC News/Discovery News National Poll, conducted by Chilton Research Company: May 27, 1997, as reported by ABCNEWS.com, May 29, 1997 (Sample size: 517).

Lake Research Poll, February 1997

* 68 percent of respondents said that the federal government should not punish doctors who prescribe marijuana
* 60 percent of respondents said that doctors should "be able to prescribe marijuana for medical purposes"
* Source: Lake Research National for The Lindesmith Center: February 5-9, 1997 (Sample size: 1,002).

California Field Poll, October 1996

* 59 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.
* Source: California Field Poll of statewide voters, conducted by The Field Institute: October 25-28, 1996, as reported by *The San Francisco Chronicle*, October 30, 1996 (Sample size: 824).

Fairbanks, Maslin, Maullin & Associates California Voter Poll, October 1996

* 95 percent of respondents have ever heard "anything about marijuana being used for medical purposes."
* 62 percent of respondents said they approved of the California Medical Marijuana Initiative.
* Source: California Voter Poll conducted by Fairbanks, Maslin, Maullin & Associates for Californians for Medical Rights: June 5, 1997 (Sample size: 800).

Los Angeles Times Poll, October 1996

* 58 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.
* Source: *Los Angeles Times* telephone poll of California adults, as reported by the *Los Angeles Times*, October 25, 1996 (Sample size: not available).

California Field Poll, October 1996

* 62 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: California Field Poll of statewide voters, conducted by The Field Institute: October 7-9, 1996, as reported by *The San Francisco Chronicle,* October 15, 1996 (Sample size: 505).

California Field Poll, September 1996

* 62 percent of respondents supported legalizing marijuana for medical use under a doctor's supervision.

* Source: California Field Poll of statewide voters, conducted by The Field Institute: August 29-September 7, 1996, as reported by *The San Francisco Chronicle,* September 19, 1996 (Sample size: 416).

American Civil Liberties Union Poll, November 1995

* 85 percent of respondents favored "making marijuana legally available for medical uses where it has been proven effective for treating a problem."

* 55 percent of respondents favor "making marijuana legally available for medical uses, even though testing has not been complete.'

* Source: "Questionnaire and Topline Results from a [National] Poll Regarding Marijuana for the American Civil Liberties Union," conducted by Belden & Russonello Research and Communications: March 31-April 5, 1995 (Sample size: 1,001).

Binder Research Poll, March 1995

* 65.5 percent of respondents said they support ending "the prohibition of marijuana for personal medical use."

* Source: California Voter Survey, conducted by David Binder Research: March 2-8, 1995 (Sample size: 750).

Boston Globe Reader Feedback Poll, September 1994

* 98.6 percent of respondents said they favored "legalizing marijuana for medical use."
* Source: *Boston Globe* Call-In Poll as reported by *The Boston Globe*, September 15, 1994 (Sample size: 1,320).

CANADA:

Decima Research Inc., April 1999

* 78 percent of respondents "strongly agree or agree with the government's consideration of legalizing marijuana as a medical treatment."
* Source: DRI poll as reported by the *Edmonton Sun*, April 7, 1999 (Sample size: 2,026).

CTV/Angus Reid Poll, November 1997

* 83 percent of respondents supported legalizing medical marijuana.
* Source: Angus Reid Poll, conducted October 23-28, 1997, as reported by the *Canada Globe and Mail*, November 4, 1997 (Sample Size: 1,515).

UNITED KINGDOM:

British Broadcasting Network (BBC), July 1998

* 96 percent of respondents said marijuana should be legalized for medical purposes.
* Source: BBC1 Watchdog Healthcheck online telephone poll, conducted July 7, 1998, as reported by the *Independent* on Sunday, August 2, 1998 (Sample size: 42,000).

APPENDIX B

ORGANIZATIONS SUPPORTING MEDICAL USE OF CANNABIS 1995-1999

(source: www.norml.org/medical/mjorgs.shtml, http://www.compassionateaccess.org/signers.html)

ORGANIZATIONS SUPPORTING "SUPERVISED ACCESS" TO MEDICAL USE OF CANNABIS:

Action Council (1996)
AIDS Treatment News (1998)
Alaska Nurses Association (1998)
American Academy of Family Physicians (1995)
American Medical Student Association (1994)
American Preventive Medical Association (1994)
American Public Health Association (1994)
American Society of Addiction Medicine (1997)
Australian National Task Force on Cannabis (1994)
Being Alive: People With HIV/AIDS Action Committee (1996)
California Academy of Family Physicians (1994)
California Nurses Association (1995)
Colorado Nurses Association (1995)
Florida Medical Association (1997)
French Ministry of Health (1997)
Health Canada (1997)
Kaiser Permanente (1997)
Life Extension Foundation (1997)
Lymphoma Foundation of America (1997)
National Nurses Society on Addictions (1995)
New England Journal of Medicine (1997)
New Mexico Nursing Association (1997)
New York State Nurses Association (1995)
North Carolina Nurses Association (1996)
San Francisco Mayor's Summit on AIDS and HIV (1998)

Virginia Nurses Association (1994)
Whitman-Walker Clinic (1998)

ORGANIZATIONS SUPPORTING "LEGAL ACCESS TO MARIJUANA UNDER A PHYSICIAN'S RECOMMENDATION":

Alaska Nurses Association (1998)
California Academy of Family Physicians (1996)
California Nurses Association (1995)
Los Angeles County AIDS Commission (1996)
Maine AIDS Alliance (1997)
San Francisco Medical Society (1996)
Whitman-Walker Clinic (1998)

ORGANIZATIONS SUPPORTING A PHYSICIAN'S RIGHT TO RECOMMEND OR DISCUSS CANNABIS THERAPY WITH A PATIENT:

American Medical Association (1997)
American Society of Addiction Medicine (1997)
Bay Area Physicians for Human Rights (1997)
Being Alive: People with HIV/AIDS Action Committee (1997)
California Academy of Family Physicians (1997)
California Medical Association (1997)
Gay and Lesbian Medical Association (1997)
Marin Medical Society (1997)
New Mexico Board of Nursing (1997)
San Francisco Medical Society (1997)

ORGANIZATIONS SUPPORTING MEDICAL RESEARCH CANNABIS:

American Cancer Society (1997)
American Medical Association (1997)
American Public Health Association (1994)
American Society of Addiction Medicine (1997)
Australian National Task Force on Cannabis (1994)
British Medical Association (1997)
British Medical Journal (1998)
California Medical Association (1997)
California Society on Addiction Medicine (1997)

Congress on Nursing Practice (1996)
Federation of American Scientists (1994)
Florida Medical Association (1997)
Gay and Lesbian Medical Association (1995)
Health Canada (1997)
Kaiser Permanente (1997)
Lymphoma Foundation of America (1997)
NIH Workshop on the Medical Utility of Marijuana (1997)
National Nurses Society on Addictions (1995)
North Carolina Nurses Association (1996)
San Francisco Medical Society (1996)

APPENDIX C

STATEMENTS OF SOME OF THE ORGANIZATIONS IN APPENDIX B

AIDS Action Council

DATE: November 1996

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "[The] AIDS Action Council supports the elimination of federal restrictions that bar doctors from prescribing marijuana for medical use by individuals with HIV/AIDS. . . . [The] AIDS Action Council supports reopening the U.S. Public Health Services Investigational New Drug Compassionate Access [Compassionate IND] program to provide access to medical-use marijuana for greater numbers of qualified patients."

* REFERENCE: "Resolution in Support of Access to Medical-Use Marijuana," adopted by the Public Policy Committee of AIDS Action Council, November 15, 1996

AIDS Treatment News

DATE: January 1998

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "The scientific case for medical [marijuana] use keeps growing stronger. Far more dangerous psychoactive drugs, like morphine, are successfully allowed in medical use. Somehow marijuana has become a symbolic or political hard line to be maintained by anti-drug believers regardless of human cost. The costs will mount until the public can organize itself to insist that those who urgently need this medicine can obtain and use it legally."

* REFERENCE: AIDS Treatment News, #287, January 23, 1998

American Academy of Family Physicians

DATE: 1995

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "The American Academy of Family Physicians [supports] the use of marijuana . . . under medical supervision and control for specific medical indications."

* REFERENCE: 1996-1997 AAFP Reference Manual – Selected Policies on Health Issues

American Cancer Society

DATE: July 1997

* POSITION: research

* SUPPORTING STATEMENTS: "[California Senate Bill] 535 focuses on medical marijuana research. [The] American Cancer Society . . . supports S.B. 535 because it is consistent with our long-held position of supporting research of any agent or technique for which there may be evidence of a therapeutic advantage."

* REFERENCE: letter from ACS to California State Senator John Vasconcellos (July 24, 1997)

American Medical Association (AMA)

DATE: December 1997

* POSITION: endorsement of a physicians' right to discuss marijuana therapy with a patient

* SUPPORTING STATEMENT: "The AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions."

* POSITION: research

* SUPPORTING STATEMENT: "The AMA recommend that adequate and well-controlled studies of smoked marijuana be conducted in patients who

have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy in including AIDS wasting syndrome, severe acute or delayed emesis induced by chemotherapy, multiple sclerosis, spinal cord injury, dystonia, and neuropathic pain."

* REFERENCE: Council on Scientific Affairs Report #10: Medical Marijuana

American Medical Student Association

DATE: March 1993

* POSITION: prescriptive access

* SUPPORTING STATEMENT: "The American Medical Student Association strongly urges the United States Government . . . to meet the treatment needs of currently ill Americans by restoring the Compassionate IND [Investigational New Drug] program for medical marijuana, and . . . reschedule marijuana to Schedule II of the Controlled Substances Act, and . . . end the medical prohibition against marijuana."

* REFERENCE: AMSA House of Delegates Resolution #12

American Preventive Medical Association

DATE: December 1997

* POSITION: prescriptive access

* SUPPORTING STATEMENT: "Marijuana should be available for appropriate medicinal purposes, when such use is in accordance with state law, and that physicians who recommend and prescribe marijuana for medicinal purposes in states where such use is legal, should not be censured, harassed, prosecuted or otherwise penalized by the federal government."

* REFERENCE: "Medicinal Use of Marijuana" policy statement: December 8, 1997

American Public Health Association

DATE: November 1994

* POSITION: prescriptive access and research
* SUPPORTING STATEMENT: "Understanding that marijuana has an extremely wide acute margin of safety for use under medical supervision . . . [and] concluding that greater harm is caused by the legal consequences of its prohibition than possible risks of medicinal use; therefore [the APHA] encourages research of the therapeutic properties of various cannabinoids and combinations of cannabinoids, and . . . urges the Administration and Congress to move expeditiously to make cannabis available as a legal medicine."
* REFERENCE: Resolution #9513: "Access to Therapeutic Marijuana/Cannabis"

American Society of Addiction Medicine (ASAM)

DATE: April 1997

* POSITION: prescriptive access and research
* SUPPORTING STATEMENTS: "Approved medical uses for marijuana or [THC] for treatment of glaucoma, illnesses associated with wasting such as AIDS, the emesis associated with chemotherapy, or other uses should be carefully controlled. The drug should be administered only under the supervision of a knowledgeable physician. Research on marijuana, including both basic science and applied clinical studies, should receive increased funding and appropriate access to marijuana for study."
* POSITION: endorsement of physicians right to discuss marijuana therapy with a patient
* SUPPORTING STATEMENT: "Physicians should be free to discuss the risks and benefits of medical use of marijuana."
* REFERENCE: ASAM "Statement on Marijuana," passed by ASAM Board of Directors: April 16, 1997

Australian National Task Force on Cannabis

DATE: March 1994

* POSITION: prescriptive access and research
* SUPPORTING STATEMENTS: "First, there is good evidence that THC is an effective anti-emetic agent for patients undergoing cancer chemotherapy. . . . Second, there is reasonable evidence for the potential efficacy of THC and marijuana in the treatment of glaucoma, especially in cases which have proved resistant to existing anti-glaucoma agents. Further research is . . . required, but this should not prevent its use under medical supervision in poorly controlled cases. . . . Third, there is sufficient suggestive evidence of the potential usefulness of various cannabinoids as analgesic, anti asthmatic, anti-spasmodic, and anti-convulsant agents to warrant basic pharmacological and experimental investigation and . . . clinical research into their effectiveness. " . . . Despite the positive appraisal of the therapeutic potential of cannabinoids . . . , they have not been widely used. . . . Part of the reason for this is that research on the therapeutic use of these compounds has become a casualty of the debate in the United States about the legal status of cannabis. . . . As a community we do not allow this type of thinking to deny the use of opiates for analgesia. Nor should it be used to deny access to any therapeutic uses of cannabinoid derivatives that may be revealed by pharmacological research."
* REFERENCE: Australian National Task Force on Cannabis: "The health and psychological consequences of cannabis use"

Bay Area Physicians for Human Rights

DATE: January 1997

* POSITION: endorsement of a physician's right to recommend marijuana therapy to a patient
* SUPPORTING STATEMENT: N/A

* REFERENCE: plaintiff in *Conant v McCaffrey,* a class action suit filed in federal court in San Francisco on January 14, 1997, seeking an injunction blocking federal officials from taking any punitive action against physicians who recommend the use of marijuana to their patients

Being Alive: People With HIV/AIDS Action Committee
DATE: January 1996
* POSITION: legal access under a physician's supervision; prescriptive access
* SUPPORTING STATEMENT: "Being Alive has always supported a person's right to choose their own treatment modalities including . . . efforts to legalize medical marijuana."
* REFERENCE: letter from Executive Director Gary Costa supporting the efforts of Californians for Compassionate Use (January 3, 1996)
DATE: January 1997
* POSITION: endorsement of physician's right to recommend marijuana therapy to a patient
* SUPPORTING STATEMENT: N/A
* REFERENCE: plaintiff in *Conant v. McCaffrey, supra.*
DATE: November 1997
* POSITION: prescriptive access to active chemicals in marijuana; research
* SUPPORTING STATEMENTS: "Present evidence indicates that [cannabinoids] are remarkably safe drugs, with a side-effects profile superior to many drugs used for the same indications. . . . [The BMA] will urge the government to] consider changing the Misuse of Drugs Act to allow the prescription of cannabinoids to patients with certain conditions causing distress that are not adequately controlled by existing treatments."
* POSITION: relaxation of present marijuana-law enforcement

* SUPPORTING STATEMENT: "While research is underway, the police, the courts, and other prosecuting authorities should be made aware of the medicinal reasons for the unlawful use of cannabis by those suffering from certain medical conditions for whom other drugs have proved ineffective."
* REFERENCE: BMA report: "Therapeutic Uses of Cannabis"

California Academy of Family Physicians

DATE: February 1994
* POSITION: prescriptive access
* SUPPORTING STATEMENT: "[The CAFP] supports efforts to expedite access to cannabinoids for use under the direction of a physician."
* REFERENCE: position statement adopted by the Academy's Congress of Delegates: February 1994

DATE: August 1996
* POSITION: legal access under a physician's supervision
* SUPPORTING STATEMENT: "CAFP's support of the Medical Use of Marijuana Initiative statute, Proposition 215, is in keeping with CAFP policy."
* REFERENCE: United Press International (UPI) News Service, August 8, 1996; January 8, 1998, letter to NORML from Communications Director Alison Barnsley outlining the CAFP's stance on medical marijuana

DATE: January 1997
* POSITION: endorsement of physician's right to recommend marijuana therapy to a patient
* SUPPORTING STATEMENT: "CAFP's amicus support of the [*Conant v. McCaffrey*] lawsuit is based on the narrow issue of the right of physicians to discuss any medical topics with their patients."
* REFERENCE: filed a *amicus* brief in *Conant v. McCaffrey*, January 8, 1998, letter to NORML

California Medical Association (CMA)

DATE: April 1997

* POSITION: endorsement of physician's right to discuss marijuana therapy with a patient
* SUPPORTING STATEMENT: "[The] CMA oppose any governmental threats against physicians arising from [the] discussion of medical marijuana in the context of the established physicians-patient relationship."
* POSITION: research
* SUPPORTING STATEMENTS: "The CMA urge that carefully designed, controlled clinical trials of the effectiveness of inhaled marijuana for medical indications be allowed to proceed immediately. . . . The CMA immediately initiate efforts at the federal level to facilitate the availability of inhaled marijuana for use in conducting clinical research to determine the medical efficacy of marijuana."
* REFERENCE: CMA Resolution #107a-97: Medical Marijuana

California Nurses Association

DATE: September 1995

* POSITION: legal access under a physician's supervision
* SUPPORTING STATEMENTS: "The California Nurses Association supports AB (Assembly Bill) 1529 which would eliminate California's prohibition against possessing marijuana or growing marijuana for individuals using marijuana for medical purposes. Many patients suffering from and receiving treatment for cancer, AIDS, glaucoma, and multiple sclerosis receive relief from using marijuana. Marijuana helps patients with nausea, vomiting and muscle spasms where other medications are not effective. Currently, these patients must break the law to use marijuana to relieve their symptoms. This measure is

a compassionate alternative for patients suffering from these diseases to obtain relief."

* REFERENCE: letter from CNA President Kurt Laumann, RN, to Gov. Pete Wilson (September 21, 1995)

California Society on Addiction Medicine (CSAM)

DATE: May 1997

* POSITION: federal rescheduling and research

* SUPPORTING STATEMENTS: "CSAM supports controlled studies of the medical usefulness of marijuana, including all routes of administration, and especially supports studies on the therapeutic effects of the essential ingredients . . . of cannabis sativa. . . . CSAM urges the DEA to remove cannabis from Schedule I and move it to an appropriate Schedule, below Schedule I as determined by what is known about its therapeutic benefit."

* REFERENCE: CSAM "Position on Medical Use of Marijuana in California" as it appeared in CSAM News, Spring 1997

Colorado Nurses Association

DATE: 1995

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "The Colorado Nurses Association recognize the therapeutic use of cannabis [and] support efforts to end federal policies which prohibit or unnecessarily restrict marijuana's legal availability for legitimate health care uses. . . . Marijuana must be placed in a less restrictive Schedule and made available to patients who may benefit from its use."

* REFERENCE: Colorado Nurses Association 1995 Conventional Directory and Book of Reports

Congress of Nursing Practice

DATE: May 1996

* POSITION: instructing RN's on medical marijuana; research

* SUPPORTING STATEMENT: "The Congress of Nursing Practice . . . support education for RN's regarding current evidence based therapeutic uses of cannabis, [and] support investigation of therapeutic efficacy of cannabis in controlled trials."

* REFERENCE: Motion passed by the CNP: May 31, 1996

Federation of American Scientists

DATE: November 1994

* POSITION: research

* SUPPORTING STATEMENT: "Based on much evidence, from patients and doctors alike, on the superior effectiveness and safety of whole cannabis (marijuana) compared to other medications for many patients – suffering from the nausea associated with chemotherapy, the wasting syndrome of AIDS, and the symptoms of other illnesses – and based on the lack of incentives for profit-seeking corporations to validate the effectiveness of a medicine that cannot be patented, we hereby petition the Executive Branch and Congress to facilitate and expedite the research necessary to determine whether this substance should be licensed for medical use by seriously ill persons."

* REFERENCE: FAS Petition on Medical Marijuana

Florida Medical Association

DATE: June 1997

* POSITION: prescriptive access

* SUPPORTING STATEMENT: "The FMA urge the state and federal governments and U.S. Public Health Service to open limited access to medical

marijuana by reopening the investigational new drug [Compassionate IND] program to new applicants."
* POSITION: research
* SUPPORTING STATEMENT: "The FMA shall urge Congress, the FDA, DEA and all other relevant governmental agencies to expedite unimpeded research into the therapeutic potential of smokable marijuana."
* REFERENCE: FMA Resolution #97-61

French Ministry of Health
DATE: December 1997
* POSITION: prescriptive access
* SUPPORTING STATEMENTS: "Obviously, it should be possible to prescribe [cannabis.] For a doctor, that could be a real benefit."
* REFERENCE: statements of French Health Minister Bernard Kouchner: *Independent* on Sunday, December 7, 1997.

Gay and Lesbian Medical Association
DATE: May 1995
* POSITION: research
* SUPPORTING STATEMENT: "[We] support . . . the authorization and implementation of clinical trials of marijuana for various aspects of AIDS treatment."
* REFERENCE: Gay and Lesbian Medical Association Policy Statement #066-95-104
DATE: February 1997
* POSITION: endorsement of a physician's right to recommend marijuana therapy to a patient
* SUPPORTING STATEMENTS: "The most essential aspects of productive patient physician relationships are trust, confidentiality, and truly informed consent for all potential therapies. . . . We thus feel strongly that any threats of negative repercussions on physicians who in good faith discuss the use of marijuana

for patients who might benefit from it are an inappropriate infringement of patient physician relations. We therefore urge most strongly that . . . Physicians should not be subject to sanctions for conducting such good faith discussions."

* REFERENCE: "Medical Marijuana: A Plea For Science And Compassion," joint statement issued by The Gay and Lesbian Medical Association and The San Francisco Medical Society

Health Canada

DATE: December 1997

* POSITION: prescriptive access and research

* SUPPORTING STATEMENTS: "There is no problem, basically, with marijuana as a medicine. . . . Marijuana is no different than morphine, no different than codeine, no different than Aspirin. There just has to be a process where we are able to say [doctors] have undertaken the right experiments and produced a result that shows the benefit is greater than the risk for the individual patients."

* REFERENCE: statements of Health Canada spokesman Dann Michols: *Ottawa Citizen,* December 19, 1997

Kaiser Permanente

DATE: April 1997

* POSITION: prescriptive access and research

* SUPPORTING STATEMENTS: "Medical guidelines regarding [marijuana's] prudent use should be established. . . . Unfortunately, clinical research on potential therapeutic uses for marijuana has been difficult to accomplish in the United States, despite reasonable evidence for the efficacy of tetrahydrocannabinol (THC) and marijuana as anti-emetic and anti-glaucoma agents and the suggestive evidence for their efficacy in the treatment of other medical conditions, including AIDS."

* REFERENCE: Kaiser Permanente study: "Marijuana Use and Mortality," American Journal of Public Health, April 1997

Life Extension Foundation
DATE: March 1997
* POSITION: prescriptive access
* SUPPORTING STATEMENT: "Those of LEF's members who are resident in Arizona, California, Connecticut, and Virginia and suffer terminal illness and intractable pain are denied by the federal policy the opportunity to receive relief from medical marijuana in accordance with state law."
* REFERENCE: Complaint for declaratory judgment and injunctive relief: *Durk Pearson and Sandy Shaw et al. v. Barry McCaffrey et al.*

Los Angeles County AIDS Commission
DATE: September 1996
* POSITION: legal access under a physician's supervision
* SUPPORTING STATEMENT: N/A
* REFERENCE: Resolution # unavailable

Lymphoma Foundation of America
DATE: January 1997
* POSITION: prescriptive access and research
* SUPPORTING STATEMENT: N/A
REFERENCE: Resolution # unavailable

Maine AIDS Alliance
DATE: December 1997
* POSITION: legal access under a physician's supervision
* SUPPORTING STATEMENT: N/A
* REFERENCE: *Bangor Daily*, December 30, 1997

Marin (California) Medical Society
DATE: February 1997
* POSITION: endorsement of a physician's right to recommend marijuana therapy to a patient
* SUPPORTING STATEMENT: N/A
* REFERENCE: filed in *amicus* brief in *Conant v. McCaffrey*

Institutes of Health (NIH) Workshop on the Medical Utility of Marijuana
DATE: August 1997
* POSITION: research
* SUPPORTING STATEMENTS: "The scientific process should be allowed to evaluate the potential therapeutic effects of marijuana for certain disorders, dissociated from the societal debate over potential harmful effects of nonmedical marijuana use. . . . Marijuana looks promising enough to recommend that there be new controlled studies done. The indications in which varying levels of interest were expressed are the following: appetite stimulation/cachexia, nausea and vomiting following anti-cancer therapy, neurological and movement disorders, analgesia, [and] glaucoma. Accordingly, the NIH should consider relevant administrative mechanisms to facilitate grant applications in each of these areas. Whether or not the NIH is the primary source of grant support for a proposed bona fide clinical research study, if that study meets U.S. regulatory standards . . . protocol approval, . . . the study should receive marijuana."
* REFERENCE: Workshop on the Medical Utility of Marijuana: Report to the Director

National Nurses Society on Addictions

DATE: May 1995

* POSITION: prescriptive access and research

* SUPPORTING STATEMENTS: "Cannabis has been used medicinally throughout the world for centuries. . . . As a medicine, cannabis has been found to be effective in a) reducing intraocular pressure in glaucoma, thus preventing blindness, b) reducing nausea and vomiting associated with chemotherapy, c) stimulating the appetite for AIDS patients suffering from the wasting syndrome, d) controlling spasticity associated with spinal cord injuries and multiple sclerosis, e) increasing comfort for persons suffering from chronic pain, and f) controlling seizures for persons suffering from seizure disorders. . . . As nurses, we have an obligation to advocate for optimal health care for all individuals. Medicine which enhances quality of life for persons suffering from life and sense-threatening illnesses should not be prohibited because some persons may develop a substance abuse and/or addiction problem to that medicine. Cannabis does have therapeutic value and has a wide margin of safety, and therefore practitioners should have the right to prescribe cannabis to patients when the potential benefits surpasses [sic] the health risks. . . . The National Nurses Society on Addictions urges the federal government to remove marijuana from the Schedule I category immediately, and make it available for physicians to prescribe. NNSA urges the American Nurses' Association and other health care professional organizations to support patient access to this medicine. . . . NNSA supports research regarding the various cannabinoids and combinations thereof, to determine the greatest therapeutic potential."

* REFERENCE: "Position Paper: Access to Therapeutic Cannabis," approved by the NNSA Board of Directors: May 1, 1995

New England Journal of Medicine

DATE: January 1997

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "The advanced stages of many illnesses and their treatments are often accompanied by intractable nausea, vomiting, or pain. Thousands of patients with cancer, AIDS, and other diseases report they have obtained striking relief from these devastating symptoms by smoking marijuana. . . . Federal authorities should rescind their prohibition of the medical use of marijuana for seriously ill patients and allow physicians to decide which patients to treat. The government should change marijuana's status from that of a Schedule I drug . . . to that of a Schedule II drug . . . and regulate it accordingly."

* REFERENCE: Editorial by NEJM editor Dr. Jerome Kassirer, January 30, 1997

New Mexico State Board of Nursing

DATE: June 1997

* POSITION: endorsement of a RN's right to discuss marijuana therapy with a patient

* SUPPORTING STATEMENT: N/A

* Reference: transcript of minutes: NMSBN June 19, 1997 board meeting

New York State Nurses Association

DATE: June 1995

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "Marijuana has been found to be effective in the treatment of glaucoma by reducing intraocular pressure and in reducing nausea and vomiting caused by chemotherapy. Marijuana has also been effective in stimulating the appetite of AIDS patients suffering from the wasting syndrome, controlling spasticity in spinal cord injury

patients, and in controlling seizures for persons suffering from epilepsy and for persons with multiple sclerosis. Marijuana is remarkably non-toxic. . . . The NYSNA Peer Assistance Committee agrees with the intent and content of the resolution Legalizing Marijuana for Medical Purposes."

* REFERENCE: "Position Statement on Medicinal Marijuana," passed by the NYSNA Board of Directors: June 7, 1995

North Carolina Nurses Association

DATE: 1996

* POSITION: prescriptive access and research

* SUPPORTING STATEMENTS: "[The] NCNA urges the Administration and Congress to make cannabis available as a legal medicine where shown to be safe and effective and to immediately allow access to therapeutic cannabis through the Investigational New Drug [Compassionate IND] Program. NCNA also supports research of the therapeutic properties and combinations of the various cannabinoids and alternative methods of administration."

* REFERENCE: "Position Statement on Therapeutic Use of Cannabis," adopted by the NCNA: October 15, 1996

San Francisco Mayor's Summit on AIDS and HIV

DATE: January 1998

* POSITION: prescriptive access

* SUPPORTING STATEMENTS: "Marijuana must continue to be available to persons living with AIDS and HIV and other diseases who wish to use it for pain management, appetite stimulation and other medicinal purposes."

* REFERENCE: "Mayor's Summit on AIDS & HIV," preliminary report released January 27, 1998

San Francisco Medical Society

DATE: August 1996

* POSITION: legal access under a physician's supervision

* SUPPORTING STATEMENT: "The SFMS takes a support position on the California Medical Marijuana Initiative."

* POSITION: research

* SUPPORTING STATEMENT: "This support position also contains the provision that controlled, blinded studies be conducted to determine both the real efficacy of smoked marijuana and its relative benefits and risks compared to Marinol."

* REFERENCE: Motion passed by SFMS Board of Directors: August 8, 1996

DATE: February 1997

* POSITION: endorsement of a physician's right to recommend marijuana therapy to a patient

* SUPPORTING STATEMENT: "We . . . feel strongly that any threats of negative repercussions on physicians who in good faith discuss the use of marijuana for patients who might benefit from it are an inappropriate infringement of patient physician relations. We therefore urge most strongly that. . . . Physicians should not be subject to sanctions for conducting such good faith discussions."

* REFERENCE: "Medical Marijuana: A Plea For Science And Compassion," joint statement issued by The Gay and Lesbian Medical Association and The San Francisco Medical Society

Virginia Nurses Association

DATE: October 1994

* POSITION: prescription access

* SUPPORTING STATEMENT: "The Virginia Nurses Association supports all reasonable efforts to end federal policies which prohibit or unnecessarily restrict marijuana's legal availability for legitimate

medical uses; and be it Resolved That the Virginia Nurses Association provide education to the nurses of Virginia on the therapeutic use of marijuana and federal prohibition of its use; and be it Resolved That the Virginia Nurses Association encourage other health care provider organizations to support medical access to marijuana."

* REFERENCE: Resolution passed by the VNA Delegate Assembly: October 7, 1994

FEB 20 2001

No. 00-151

Supreme Court, U.S.
FILED
FEB 20 2001
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 2000

UNITED STATES OF AMERICA,

Petitioner,

—v.—

OAKLAND CANNABIS BUYERS' COOPERATIVE and JEFFREY JONES,

Respondents.

ON WRIT OF *CERTIORARI* TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF *AMICUS CURIAE* OF THE AMERICAN CIVIL LIBERTIES UNION, THE ACLU OF NORTHERN CALIFORNIA, THE ACLU OF SOUTHERN CALIFORNIA, AND THE ACLU OF SAN DIEGO AND IMPERIAL COUNTIES, IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI* [1]

The American Civil Liberties Union (ACLU) is a nationwide, nonprofit, nonpartisan organization with approximately 300,000 members dedicated to the principles of liberty and equality embodied in the Constitution and this nation's civil rights laws. The ACLU has three regional affiliates in the State of California: the ACLU of Northern California, the ACLU of Southern California, and the ACLU of San Diego and Imperial Counties. All three California affiliates of the ACLU supported passage of the medical marijuana initiative, Proposition 215, which led directly to the events giving rise to this litigation. More generally, the ACLU has participated in numerous cases before this Court, both as direct counsel and as *amicus curiae,* to defend the principle that the war on drugs should not be pursued at the expense of traditional legal and constitutional safeguards designed to restrain the government from overreaching in its law enforcement efforts. The proper resolution of this case is therefore a matter of substantial importance to the ACLU and its members throughout the country.

STATEMENT OF THE CASE

On November 5, 1996, the people of California passed Proposition 215, the "Compassionate Use Act of 1996." *See* Cal. Health & Safety Code §11362.5. It is now state law that "seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use

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[1] Letters of consent to the filing of this brief have been lodged with the Clerk of the Court pursuant to Rule 37.3. Pursuant to Rule 37.6, counsel for *amici* states that no counsel for a party authored this brief in whole or in part and no person, other than *amici*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana." *Id.* at §11362.5(b)(1)(A).

Following passage of Proposition 215, the Oakland Cannabis Buyers' Cooperative ("OCBC") organized a dispensary to provide patients a safe and affordable source of marijuana for medical use. On July 28, 1998, the City of Oakland ("the City"), acting in order "to recognize and protect the rights of patients," and acknowledging the need for "safe and affordable medical cannabis," passed an ordinance establishing a Medical Cannabis Distribution Program. J.A. 139. On August 11, 1998, the City designated OCBC to administer the program. J.A.141, 145.

Reacting to the California proposition and to similar ballot initiatives in other states, the United States filed suit against OCBC on January 9, 1998. The federal government argued that even though California voters have altered state law to permit the use of marijuana for medical purposes, California voters cannot change the fact that the manufacture or distribution of marijuana is illegal under the federal Controlled Substances Act ("CSA"). *See* 21 U.S.C. §841(a)(1).

Instead of seeking to enforce federal law in the usual way -- by criminally prosecuting OCBC before a jury -- the United States asked the district court to pursue the highly unusual course of prohibiting OCBC from continuing its activities. It did so under a rarely used provision of the CSA that empowers federal prosecutors to circumvent ordinary criminal procedures by requesting instead a prospective injunction against illegal activity. *See* 21 U.S.C. §882.[2]

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[2] Section 882 provides, in full:

(continued...)

On May 19, 1998, the district court preliminarily enjoined OCBC from violating the CSA. *See United States v. Cannabis Cultivators Club*, 5 F.Supp.2d 1086, 1106 (N.D. Cal. 1998). The court expressed doubt regarding the validity of a necessity defense, but deferred any definitive ruling on that issue, reasoning that if and when the federal government alleged that OCBC had violated the injunction, OCBC could raise the necessity defense in a contempt proceeding. *See id.* at 1102.

OCBC was in fact subsequently held in contempt. *See United States v. Cannabis Cultivators Club*, No. 98-00088, slip op. at 12 (N.D. Cal. Oct. 13, 1998). In the contempt proceeding, the court denied OCBC's request for a jury trial notwithstanding §882(b), observing that "this is not a criminal proceeding in which a defendant is entitled to a jury trial even if there are no disputes of fact," *id.*, and noting the applicability of judgment as a matter of law under Fed.R. Civ.P. 50, a procedure not available in a criminal trial. *Id.* It also applied a "clear and convincing" burden of proof, not the more demanding "beyond a reasonable doubt" standard that would have applied in a criminal prosecution. *See id.*

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[2] (...continued)

(a) Jurisdiction

The district courts of the United States and all courts exercising general jurisdiction in the territories and possessions of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter.

(b) Jury trial

In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, upon demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure.

Finally, the court granted the government's motion to exclude the medical necessity defense from the contempt proceedings, on the ground that OCBC had not presented sufficient evidence of necessity. *See id.* at 7-8.

Three days later, the district court denied OCBC's motion to modify the injunction to allow the provision of marijuana to patients who have no alternative to cannabis for the treatment of the most serious illnesses. *See United States v. Cannabis Cultivators Club*, No. 98-00088, slip op. at 2 (N.D. Cal. Oct. 16, 1998).[3]

On appeal, the Ninth Circuit reviewed the district court's ruling on OCBC's motion to modify the injunction. *See United States v. Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109, 1111 (9th Cir. 1999)("*OCBC*").[4] The Ninth Circuit remanded for reconsideration of the district court's denial of the motion to modify the injunction, holding that the district court had erred in concluding that it "lacked the power to make the requested modification." *Id.* at 1114. The Ninth Circuit quoted the district court's October 13, 1998 ruling, in which the trial court explained that it had no power to circumscribe the injunction once it found a statutory violation:

> The Court understands [OCBC's] argument that in this action the Court is sitting in equity and

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[3] In reaction to the federal government shutdown of OCBC, the City of Oakland has declared a public health emergency. J.A.147-51. The City expressed concern that "the closure of [OCBC] will cause pain and suffering to seriously ill Oakland residents." J.A.149. The Oakland City Council has renewed that resolution every two weeks. *See, e.g.*, J.A. 152-57.

[4] OCBC's appeal from the contempt order was deemed moot because OCBC had purged the contempt by agreeing to comply with the injunction. 190 F.3d at 1113.

> therefore must consider the human suffering that will be caused by [the government's] success in closing down the OCBC. While the Court is sitting in equity, however, its equitable powers do not permit it to ignore federal law. Federal law prohibits the distribution of marijuana to seriously ill persons for their personal medical use.

See Cannabis Cultivators Club, slip op. at 13 (N.D. Cal. Oct. 13, 1998)(quoted in part by *OCBC*, 190 F.3d at 1114). The court of appeals ruled that the district court did not lose the power under §882 to refuse to enjoin a particular group of people whenever it found a violation of the CSA. On the contrary, "there is no evidence that Congress intended to divest the district court of its broad equitable discretion." *OCBC*, 190 F.3d at 1114. Moreover, the court of appeals found that the district court not only has the *power* to consider the pain and suffering of a group, but it has the *duty* to do so as part of its equitable inquiry into the public interest. *See id.* To be sure, the court of appeals also touched on the medical necessity defense. *See id.* It concluded that the district court could consider, as *part* of its equitable calculus, that a "legally cognizable defense" would have been available to OCBC if the government had chosen to use the normal criminal processes. *Id.* But in none of the judgments on review here did the district court or the court of appeals ever rule on the validity of the legal necessity defense under the CSA. Instead, the court of appeals remanded so the district court could exercise its power to consider the full range of equities.

On remand, the OCBC renewed its motion to modify the injunction. The district court granted the motion after balancing the equities, as instructed by the court of appeals. *See United States v. Oakland Cannabis Buyers' Coop.*, No. 98-00088, slip op. at 1 (N.D. Cal. July 17, 2000). This

Court subsequently stayed the district court's order "pending final disposition of the appeal by the United States Court of Appeals for the Ninth Circuit and further order of this Court." *See United States v. Oakland Cannabis Buyers' Coop.*, __ U.S. __, 121 S.Ct. 21-22 (2000). Before the Ninth Circuit reviewed the district court's modification, this Court granted *certiorari* to review the Ninth Circuit's initial opinion. *See United States v. Oakland Cannabis Buyers' Coop.*, __ U.S. __, 121 S.Ct. 563 (2000).

SUMMARY OF ARGUMENT

Notwithstanding the government's question presented, the validity of a medical necessity defense for marijuana distribution is not properly before this Court. In our view, the *only* issue actually and necessarily presented for review is the following: Does §882, the provision of the Controlled Substances Act that grants jurisdiction to enjoin statutory violations, strip all discretion from the district court, requiring it to automatically issue an injunction whenever the United States demonstrates a violation of the CSA? Or, as the plain language of the statute indicates and the principles of equity counsel, does the district court retain discretion to shape an injunction to account for all of the factors that traditionally influence the exercise of equity, including hardship to the parties (both factual and legal), the public interest, the efficacy of the proposed injunction, and any potential defenses? The district court concluded that once it found a *prima facie* violation of the CSA, it lost all power to deny or even limit an injunction. *See Cannabis Cultivators Club*, slip op. at 13 (N.D. Cal. Oct. 13, 1998). The propriety of this narrow holding is all that was reviewed by the Ninth Circuit, and all that is before this Court.

The United States urges this Court to ignore the actual holding of the Ninth Circuit and instead to issue a preemp-

tive ruling that congressional placement of marijuana in Schedule I of the CSA precludes a necessity defense.[5] The government's interpretation of the interplay between the CSA and common law defenses is wrong for the reasons stated in respondents' brief. But the analytical approach pressed by the United States carries a separate, important danger: It invites this Court to overturn longstanding jurisprudence concerning injunctions against criminal acts.

Significantly, the United States pays no heed to the actual words of 21 U.S.C. §882(a), which provide that the district court "shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations" of the CSA. Under the plain language of that section, the district court, sitting as chancellor, retains discretion to refuse to enjoin an activity or to partially enjoin an activity, even if that activity violates the statute. In making this determination, the court may of course consider

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[5] Because that issue was not resolved by either court below, the most appropriate disposition may be to dismiss the writ of *certiorari* as improvidently granted. This would allow the lower courts to consider the validity of the necessity defense in the particular context of this case in due course on remand. As described above, the district court held, in a ruling not being reviewed here (because it was part of the contempt proceeding later found moot), only that OCBC had presented insufficient facts to assert the medical necessity defense. *See Cannabis Cultivators Club*, slip op. at 7-8 (N.D. Cal. Oct. 13, 1998). The Ninth Circuit characterized the medical necessity defense as "legally cognizable," which it surely is in the abstract, but never separately addressed the significance of the Schedule I listing, presumably because it was sending the case back to the district court to allow the district court to exercise its discretionary judgment. *See OCBC*, 190 F.3d at 1114. While the government is free to present any question it wants for review, this Court has traditionally refrained from deciding important legal questions on such a barren record. *See National Collegiate Athletic Ass'n v. Smith*, 525 U.S. 459, 470 (1999)("[W]e do not decide in the first instance issues not decided below").

-- indeed, *must* credit -- the harm that might result to critically ill patients who have no alternative to using cannabis under a doctor's supervision. This Court has construed similar provisions of other statutes to preserve equity's traditional discretion, even after finding a statutory violation.

Properly read, therefore, §882 leaves intact the district court's discretion to craft an injunction that forbids marijuana distribution to moderately ill patients, while not enjoining distribution to more seriously ill patients, entirely apart from the validity of a medical necessity defense. As a matter of proportionality and balancing of hardship, a district court could well deem it appropriate that, for more seriously ill patients, the government should be held to its normal avenue of criminal prosecution. The United States thus misses the mark when it says that striking down the necessity defense for marijuana use resolves this case. This Court can reverse the decision under review here only upon finding that §882, despite its plain language, entirely eliminates the district court's discretion to consider a request for injunctive relief.

Several compelling considerations support that conclusion. First, nothing in the CSA precludes the district court from exercising its equitable discretion to account for patients' strong medical interest in avoiding physical suffering. Members of this Court, as well as a growing consensus of commentators, have recognized that seriously ill patients have a liberty interest in adequate palliative care. The district court should have recognized its ability under the statute to consider the strength of this interest in shaping its injunction.

Second, courts of equity have historically been loathe to allow the government to circumvent the due process safeguards required in a criminal prosecution by seeking to prohibit allegedly criminal behavior through a civil injunction, which could later enforced through civil contempt proceed-

ings. The reason behind that hesitance is illustrated by the facts of this case. If the district court's original injunction were allowed to stand, any future contempt proceeding would be conducted before a civil jury. *See* 21 U.S.C. §882(b). Members of OCBC who are found to have violated the injunction could then be imprisoned (albeit as a civil penalty) without a criminal trial's basic protections, including: the right to counsel, the right to present a defense, the presumption of innocence unless guilt is proven beyond a reasonable doubt, the right to confront witnesses, etc. And this assumes that a judgment of contempt is not entered before trial -- as the contempt order in this case was -- using one of the procedural devices available only in civil cases. Absent a clear statement from Congress restricting the chancellor's traditional discretion, which §882 plainly lacks, it is entirely appropriate for a court of equity to consider the impact of these diminished procedural safeguards when it decides whether an injunction should issue and how broad it should be.

Finally, the district court erred when it assumed that a medical necessity defense could automatically be raised in a subsequent contempt hearing. To the best of our knowledge, no federal court has ever allowed a necessity defense in any contempt proceeding, whether criminal or civil. Thus, the district court should have considered, as part of its equitable calculus, the possibility that a medical necessity defense could only be raised in a criminal prosecution. It need not have decided whether such a defense existed, and neither must this Court. As a court of equity, however, it should have weighed the fact that enjoining those in dire medical need might well deprive them of a substantive defense that would be available to them in a criminal prosecution.

ARGUMENT

I. THE PLAIN LANGUAGE OF §882 GIVES THE DISTRICT COURT EQUITABLE DISCRETION TO SHAPE OR LIMIT AN INJUNCTION AGAINST USE OF MARIJUANA BY PATIENTS WHO HAVE NO ALTERNATIVE FOR TREATING SERIOUS ILLNESS

Section 882 provides that the district court "shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure to enjoin violations of this subchapter." 21 U.S.C. §882. The text of this provision merely *authorizes* the court to provide injunctive relief. Nowhere does the section eliminate or constrain the longstanding latitude afforded to courts in the exercise of their equitable jurisdiction, and it certainly does not *require* the court to enjoin all conduct found to violate the CSA.

"The starting point in interpreting a statute is its language, for if the intent of Congress is clear, that is the end of the matter." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 409 (1993)(internal quotation marks omitted); *see also Maine v. Thiboutot*, 448 U.S. 1, 6 n.4 (1980); *Middlesex County Sewerage Auth. v. National Sea Clammers Ass'n*, 453 U.S. 1, 30 n.12 (1981)(Stevens, J., concurring in part) ("the 'plain language' rule of statutory construction . . . has dominated our recent statutory decisions"). To prevail on the plain language of the statute, therefore, the government must argue that the phrase "shall have jurisdiction" in §882 means not only that the court has equitable power to issue an injunction, but that it must mechanically do so in all circumstances. The government's argument, however, has less to do with the actual wording of §882 than with the "subordination of explicit . . . text to currently favored public policy." *Maryland v. Craig*, 497 U.S. 836, 861 (1990)(Scalia, J., dissenting). In our view, therefore, this Court's in-

quiry should end with a finding that the court of appeals correctly instructed the district court that it had discretion, based on equitable considerations, to refuse to enjoin the OCBC from distributing marijuana to those in dire medical need.[6]

The legislative history, to the extent that it is relevant, fully supports that conclusion. Congressional statements explaining §882 confirm what is obvious from the text of the statute: that the provision merely "*authorizes* U.S. courts to issue injunctions against violators of [the CSA]." H.R. Rep. No. 1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 1970 WL 5971, at *132 (emphasis added). In short, §882 confers equitable authority on the district court that is permissive, not mandatory.

Section 882 and the latitude it affords are in no way anomalous: Courts have interpreted numerous similarly worded statutes according to their plain language to preserve judicial discretion to shape a statutory injunction according to equity, rather than reading them to require rote issuance of a sweeping injunction against all activity that violates the statute. For example, §17 of the Fair Labor Standards Act ("FLSA") provides that "[t]he district courts . . . shall have jurisdiction, for cause shown, to restrain violations of . . . this title." 29 U.S.C. §217. Construing this provision, this Court noted that even where a violation of the FLSA was all but established, "it will still be within the discretion of the

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[6] The district court concluded that it had no discretion under §882. *See Cannabis Cultivators Club*, slip op. at 13 (N.D. Cal. Oct. 13, 1998) ("While the Court is sitting in equity, its equitable powers do not permit it to ignore federal law"). As explained above, the Ninth Circuit remanded, not with explicit instructions that the injunction must be modified, but rather to correct the district court's misapprehension and allow it to exercise its equitable discretion as permitted under §882. *See OCBC*, 190 F.3d at 1115.

District Court whether or not to issue an injunction." *Mitchell v. Lublin, McGaughy, & Assocs.*, 358 U.S. 207, 215 (1959); *see also Martin v. Coventry Fire Dist.*, 981 F.2d 1358, 1362 (1st Cir. 1992)(Breyer, C.J.)(allowing the district court to refuse to enjoin a violation of the FLSA, based on a consideration of the equities); *Brennan v. Saghatelian*, 514 F.2d 619, 621-22 (9th Cir. 1975)(same); *Mitchell v. Hodges Contracting Co.*, 238 F.2d 380, 381 (5th Cir. 1956)(same). In a case strikingly similar to the present matter, the court of appeals reversed a district court's broad injunction, issued under the mistaken belief that it lacked the power to refuse equitable relief once it found a violation of the FLSA. *See Schultz v. Mistletoe Express Serv., Inc.*, 434 F.2d 1267, 1271 (10th Cir. 1970). In just the same way, the district court here mistakenly thought it was compelled to issue an injunction because "its equitable powers do not permit it to ignore federal law." *OCBC*, 190 F.3d at 1114 (quoting district court order).

In a similar vein, the Court in *Mills v. Electric Auto-Lite Co.*, 396 U.S. 375 (1970), construed the closely analogous language of §27 of the Securities Act of 1934, 15 U.S.C. §78aa, to mean that "nothing in the statutory policy requires the court to unscramble a corporate transaction merely because a violation occurred. In selecting a remedy the lower courts should exercise the sound discretion which guides the determinations of courts of equity . . . ." 396 U.S. at 386 (internal quotation marks omitted). Moreover, the Court only recently interpreted another similarly worded provision, §505(a) of the Federal Water Pollution Control Act, 33 U.S.C. §1365(a), to mean that "a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 192 (2000)(internal quotation marks omitted); *see also Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982)

(acting under §1365(a) and holding that "[t]he grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances"); *NRDC v. Texaco Ref. & Mktg., Inc.*, 906 F.2d 934, 937-41 (3d Cir. 1990)(construing §1365(a)); *United States v. Article of Drug*, 362 F.2d 923, 928 (3d Cir. 1966)(construing the injunction provision of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §332(a)).

The government here argues that §882 requires the district court to automatically enter an injunction, regardless of any equitable inquiry into the public interest, once it finds that the OCBC's activity violates the CSA. The government assumes that the OCBC could have no possible defense for its actions, a leap of logic that OCBC strongly disputes. But even if the necessity defense were to have no application here, the sole fact that certain activity violates a statute could not override a court's duty to balance the range of equities in deciding whether to issue an injunction. Section 882 grants jurisdiction to enjoin statutory violations; it does not command the district court to do so. *See Miller v. California Pac. Med. Ctr.*, 991 F.2d 536 (9th Cir. 1993)(Kozinski, J.)(construing the injunction provision of the National Labor Relations Act, 29 U.S.C. §160(j)), *aff'd upon reh'g en banc*, 19 F.3d 449, 457 (1994).

In *Miller*, the court rejected, in an analogous context, the argument that the government is making here. The *Miller* court held explicitly that the NLRA provision granting "jurisdiction" to temporarily enjoin unfair labor practices did not alter the "fundamental principle that an injunction is an equitable remedy that does not issue as of course." 991 F.2d. at 539 (internal quotation marks omitted). The Ninth Circuit expressed understanding that courts must consider the public interest when exercising their discretion to enter an injunction. But it also recognized that mere recitation of the statutory purpose does not automatically settle the public

interest inquiry. *See id.* at 540-41. Otherwise, an injunction would automatically issue whenever the court found a statutory violation -- a rule that all of the cases cited above, which construe similar statutes, have explicitly rejected. The *Miller* court acknowledged that an injunction must be consistent with statutory policies, as the government argues here, but emphatically concluded that "none of this contradicts the fundamental principle that injunctions are equitable in nature and should only issue when supported by the equities." *Id.* at 540. Nothing in the similar jurisdiction-granting language of §882 compels the conclusion that a court of equity must automatically enter an injunction upon finding a statutory violation.[7]

Moreover, even where the provision's language is far more mandatory than that of §882, this Court has interpreted law enforcement injunction provisions to allow full discretion not to enjoin statutory violations. For instance, §205(a) of the Emergency Price Control Act provides that "upon a showing" of current or imminent violation, equitable relief "*shall* be granted." 50 U.S.C.A. App. §925(a) (emphasis added)(quoted in *Hecht Co. v. Bowles*, 321 U.S. 321, 321 (1944)). Despite that obligatory phrasing, the Court con-

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[7] Likewise, nothing in *United States v. Rutherford*, 442 U.S. 544 (1979), suggests that an injunction against OCBC must automatically issue. *See* Pet.Br. at 44-45. The circumstances of that case were entirely different. There, terminally ill cancer patients asked the court to enjoin the *government* from interfering in any way with distribution of the drug Laetrile. Such an injunction would have prevented the government from taking *any* steps to prevent use of the drug by such patients. Here, by contrast, the government is asking the court to enjoin OCBC from distributing cannabis to *patients*. Nothing prevents the government from pursuing a criminal prosecution against OCBC for distributing marijuana to patients in dire medical need if distribution to those patients were excluded from the injunction. Because the government has a viable alternative at law, the district court has full discretion to exercise its equitable discretion -- and in fact must do so.

cluded that only a more explicit signal would evidence a congressional intent to cabin the traditional discretion of district courts to refuse to enjoin violations of federal law:

> A grant of jurisdiction to issue compliance orders hardly suggests an absolute duty to do so under any and all circumstances. We cannot but think that if Congress had intended to make such a drastic departure from the traditions of equity practice, an unequivocal statement of its purpose would have been made.

Hecht, 321 U.S. at 329. Not only is there no such clear statement here, but the plain language of §882 is entirely permissive; it contains none of the mandatory terminology included in the statute at issue in *Hecht*.

Provisions granting equitable jurisdiction to enjoin crimes, like the one at issue here, have their historical origins in legislators' desire to overcome the rule that a chancellor has no jurisdiction to enjoin a crime, *see In re Sawyer*, 124 U.S. 200, 210 (1888)(citing *Gee v. Pritchard*, 2 Swanst. 402, 413 (1818)), not any intent to abolish the traditional discretion of a court of equity. Before such jurisdiction-expanding statutes were enacted, courts of equity could enjoin criminal activity only where that activity also endangered property rights or constituted a public nuisance. *See* 124 U.S. at 210; *In re Debs*, 158 U.S. 564, 593-94 (1895)(public nuisance); *Attorney-General v. Utica Insurance Co.*, 2 Johns. Ch. 371, 1817 WL 1582, at *5 (N.Y. Ch. 1817)(property rights); *see also* Harmon Caldwell, "Injunctions Against Crime," 26 Ill.L.Rev. 259, 260-61 (1931); Edwin S. Mack, "The Revival of Criminal Equity," 16 Harv.L. Rev. 389, 392 (1903); Charles Noble Gregory, "Government By Injunction," 11 Harv.L.Rev. 487, 489 (1898). During the nineteenth century, legislatures began to expand the jurisdiction of the chancellor, at first by declaring certain

activities to be nuisances, and then increasingly without reference to the nuisance terminology. *See* 4 John Norton Pomeroy, A TREATISE ON EQUITY JURISPRUDENCE §1349 (5th ed. 1941); "Development in the Law -- Injunction, The Changing Limits of Injunctive Relief," 78 Harv.L.Rev. 997, 1014-15 (1965); Zechariah Chafee, "The Progress of the Law, 1919-20: Equitable Relief Against Torts," 34 Harv.L.Rev. 388, 398-99 (1921). But whether the legislature expanded the definition of nuisance, or simply established an equitable remedy, these jurisdiction-expanding statutes did not oust the other traditional rules of equity. *See* William H. Dunbar, "Government By Injunction," 13 L.Q.Rev. 347, 356-57 (1897). From the outset, statutes that granted "jurisdiction in equity" for law enforcement made injunctive relief "discretionary with the court." Note, "Statutory Extension of Injunctive Law Enforcement," 45 Harv.L.Rev. 1096, 1099, 1100 n.37 (1932). In sum, the historical rationale behind the ancestors of §882 was simply to grant courts of equity jurisdiction over law enforcement, not to restrict equity's traditional discretion to stay its hand.

A. Section 882 Should Be Construed To Allow The District Court To Consider Patients' Strong Interest In Treating Severe Physical Suffering

Perhaps most troubling, the government's reading of §882 -- which strips the district court of all discretion to consider equitable factors -- prevents the district court from considering the hardship to gravely ill patients caused by the government's proposed injunction. Unrelieved physical anguish is no ordinary hardship; indeed this Court's recent cases have recognized patients' important interest in avoiding serious pain, nausea, and other medical suffering.

Patients who suffer from terminal illnesses, or who require medication in order to bear the effects of life-

prolonging treatment, have a strong liberty interest in effective palliative care. For some such patients, marijuana is the only medicine that works. At least in considering whether to grant an injunction -- that is, whether to exercise its equitable powers -- the district court should have recognized its power to consider this interest. A construction of §882 that gives courts such power only bolsters the plain language of that statute.

Members of this Court recognized the fundamental liberty interest in palliative care in *Vacco v. Quill*, 521 U.S. 793 (1997), and *Washington v. Glucksberg*, 521 U.S. 702 (1997). In those cases, the Court held that state statutes banning assisted suicide were facially constitutional. Members of the Court indicated, however, that a liberty interest would exist under more particularized circumstances, where a patient was subjected to unrelieved pain or other suffering due to inadequate palliative medicines. Justice O'Connor, for instance, signed on to the majority opinion only under a specific understanding of the limits of its holding:

> The parties and *amici* agree that in these States a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death. In this light, even assuming that we would recognize such an interest, I agree that the State's interests in protecting those who are not truly competent or facing imminent death, or those whose decisions to hasten death would not truly be voluntary, are sufficiently weighty to justify a prohibition against physician-assisted suicide.

Vacco, 521 U.S. at 736 (O'Connor, J., concurring). In the

final paragraph of her opinion, Justice O'Connor reiterated: "There is no dispute that dying patients in Washington and New York can obtain palliative care, even when doing so would hasten their deaths." *Id.* at 737-38. Justice Ginsburg too concurred only in the judgments, noting explicitly that she was doing so "for the reasons stated by Justice O'Connor." *Id.* at 789.

Justice Stevens, concurring only in the judgment, recognized the liberty interest in adequate palliative care even more explicitly than Justice O'Connor:

> Avoiding intolerable pain and the indignity of living one's final days incapacitated and in agony is certainly at the heart of the liberty to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life.

Id. at 745 (Stevens, J., concurring in the judgment)(internal quotation marks and alterations omitted). Like Justice O'Connor, Justice Stevens thus recognized that circumstances might arise under which patients in serious pain could succeed in a challenge to a statute that barred their access to treatment of that pain. He therefore concluded that a patient with this sort of claim "could prevail in a more particularized challenge." *Id.* at 750.

Writing the majority opinions in *Glucksberg* and *Vacco*, Chief Justice Rehnquist acknowledged the liberty interest in adequate pain treatment highlighted by Justice Stevens. In *Glucksberg*, Chief Justice Rehnquist stated that "a more particularized challenge" might succeed in another circumstance, reiterating only Justice Stevens's point that "such a claim would have to be quite different from the ones advanced by respondents here." *Glucksberg*, 521 U.S. at 735 n.24. Similarly, in *Vacco*, Chief Justice Rehnquist endorsed Justice Stevens's observation that the Court's holding "does

not foreclose the possibility that some applications of the New York statute may impose an intolerable intrusion on the patient's freedom," noting again only that such a claim would require "different and considerably stronger arguments than those advanced by respondents here." *Vacco*, 521 U.S. at 809 n.13 (internal quotation marks omitted).

Justice Breyer, apparently not satisfied with that acknowledgment, also concurred only in the judgment, endorsing Justice O'Connor's articulation of a liberty interest in palliative care. *See id.* at 789. "I believe," he emphasized, "that Justice O'Connor's views, which I share, have greater legal significance than the Court's opinion suggests." *Id.* Strong support could be marshalled for a liberty interest, Justice Breyer argued -- a crucial component of which would be "avoidance of unnecessary and severe physical suffering." *Id.* at 790. He explained:

> Were the legal circumstances different -- for example, were state law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life -- then the law's impact upon serious and otherwise unavoidable physical pain (accompanying death) would be more directly at issue. And as Justice O'Connor suggests, the Court might have to revisit its conclusions in these cases.

Id. at 792. Justice Souter also acknowledged the importance of receiving adequate treatment for pain, implying that if the states did not adequately address the circumstances surrounding terminal illness, federal intervention might well be warranted. *See Glucksberg*, 521 U.S. at 782. In all, the opinions in *Glucksberg* and *Vacco* lend considerable authority to an individual liberty interest in adequate pain treatment, especially near the end of life, but also by implication

during any serious illness. Government efforts to frustrate such a strong interest should be viewed extremely skeptically, especially by a court sitting in equity.

A growing consensus of commentators has recognized a strong individual interest in adequate palliative care. *See, e.g.*, Jesse H. Choper, "On the Difference in Importance Between Supreme Court Doctrine and Actual Consequences," 19 Cardozo L.Rev. 2259, 2280 (1998); Yale Kamisar, "Physician-Assisted Suicide," 82 Minn.L.Rev. 895, 908-09 (1998); Larry I. Palmer, "Institutional Analysis and Physicians' Rights After *Vacco v. Quill*," 7 Cornell J.L. & Pub. Pol'y 415, 426 (1998); Robert A. Burt, "The Supreme Court Speaks: Not (Yet) Assisted Suicide, But a Constitutional Right to Palliative Care," 337 New Eng. J.Med. 1234 (1997).

The district court in this case rejected a similar argument, but only on the mistaken belief that it had no jurisdiction in equity to consider the interest of dying patients in avoiding intractable suffering. *See Cannabis Cultivators Club*, 5 F.Supp.2d at 1102-03 ("[T]his defense, like the defense of necessity, is inapplicable to this injunction action"). It was exactly this mistaken view of its equity power that the Ninth Circuit rejected, and that this Court should correct with respect to the important interest in being free from pain and in prolonging life under the supervision of a physician. Section 882 cannot be read to exclude automatically such fundamental considerations the moment a court has found a statutory violation. The plain text of the statute preserves the district court's power to decide whether to issue an injunction, even after it has found a violation, and this manifest reading finds ample support in legislative history and the decisions of this Court construing similar provisions in other statutes. Consequently, §882 should be construed in accordance with its plain language to grant the district court the power to exercise its traditional equitable discretion and

to shape its injunction to take into account the fact that some of OCBC's patients are in dire medical need of the only medicine that is able to treat their pain, enable them to endure chemotherapy, and prolong their lives. At bottom, the district court should be allowed to choose between enforcing the CSA through imposition of an injunction against marijuana use or through leaving the government to prosecute patients, with its decision being guided by patients' significant interest in avoiding profoundly debilitating pain and suffering.

B. The District Court Should Be Allowed To Consider The Fact That OCBC Members Who Continue Providing Treatment To Those In Medical Need May Face Imprisonment Without The Benefit Of Criminal Due Process Safeguards

When shaping an injunction, the district court may properly consider the fact that OCBC members may be subject to imprisonment and other severe sanctions if found in contempt, without the due process safeguards that normally accompany criminal prosecution. To be sure, §882(b) provides for a jury trial, but only a civil one -- it does not guarantee the many other protections of criminal procedure, such as the right to appointed counsel, the right to confront witnesses, compulsory process for obtaining witnesses, the right to a speedy and public trial, the right to be indicted by a grand jury, the right against self-incrimination, and the presumption of innocence unless proven guilty beyond a reasonable doubt.

Our point is not that a criminal defendant facing imprisonment for civil contempt under the CSA is entitled to criminal due process protections. *See International Union, United Mineworkers of Am. v. Bagwell*, 512 U.S. 821, 832-34 (1994). To the contrary, it is the very absence of those

protections that a district court may properly take into account in deciding whether and to what extent the government may pursue its law enforcement aims by abandoning criminal prosecution in favor of civil injunction. Certainly, nothing in the language of §882 is inconsistent with that discretion, which is firmly rooted in the history of equity jurisdiction.

As legislatures increasingly authorized injunctions against criminal activity in the late nineteenth century, prominent commentators voiced loud opposition. In their view, the statutes allowed government to pursue exactly the same law enforcement goals as they would have in a criminal prosecution, without having to observe the bothersome requirements of criminal procedure. They coined the phrase "government by injunction" to characterize their protest. *See* Forrest R. Black, "The Expansion of Criminal Equity Under Prohibition," 5 Wisc.L.Rev. 412 (1930); "Recent Cases, Injunctions," 43 Harv.L.Rev. 499 (1930); Edwin S. Mack, "The Revival of Criminal Equity," 16 Harv.L.Rev. at 392; Charles Noble Gregory, "Government By Injunction," 11 Harv.L.Rev. at 489; William H. Dunbar, "Government By Injunction," 13 L.Q.Rev. at 356-57. Following these critiques, cases were brought challenging such statutes on constitutional grounds. Justice Field, then a Justice of the Supreme Judicial Court of Massachusetts, considered one such challenge, involving an injunction against the sale of intoxicating liquors:

> [T]he only effect of the injunction is to subject the respondent to the process used for punishing persons guilty of violating injunctions, in addition to, or in substitution for, criminal process. The legislature apparently thought that a remedy in equity would be more speedy or more certain or more efficient than that by complaint or indictment. The issuing of the in-

> junction of itself adds nothing to the prohibition of the statutes, but the intention plainly is to call into use the peculiar process employed by courts of equity in punishing persons guilty of willful violations of injunctions . . . . Indeed, there are many indications that the principal reason why the statute was passed was to avoid a trial by jury . . . .

Carleton v. Rugg, 22 N.E. 55, 58 (Mass. 1889)(Field, J., dissenting).[8] Despite the protests, criminal equity statutes were almost uniformly held to be constitutional. *See id.* at 57; *see also Eilenbecker v. District Ct. of Plymouth County*, 134 U.S. 31 (1890), overruled in part by *Bloom v. Illinois*, 391 U.S. 194, 195-96 (1968); *Kansas v. Ziebold*, 123 U.S. 623 (1887). *But see Hedden v. Hand*, 107 A. 285 (N.J. 1919).

Nevertheless, Congress responded to the forceful criticism levied at the increasing jurisdiction of criminal equity by passing statutes designed to preserve a criminal jury trial in certain cases. For example, §21 of the Clayton Act, passed by Congress in 1914, provided for a criminal-style jury trial, upon demand of the accused, in all contempt proceedings where violation of an injunction also constituted violation of a criminal law. *See* 18 U.S.C. §402; *see also* Felix Frankfurter & James M. Landis, "Power of Congress Over Procedure in Criminal Contempts in 'Inferior' Federal Courts -- A Study in Separation of Powers," 37 Harv.L.Rev. 1010, 1039-58 (1924)(discussing the origins of §21 of the

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[8] Here, too, federal prosecutors evidently wished to avoid a jury comprised of California voters who had only recently overwhelmingly approved Proposition 215. They have so far succeeded in this goal, obtaining both an injunction and a contempt order without confronting a jury, and without any of the other protections that would have been afforded to OCBC members in a criminal trial.

Clayton Act). Congress passed §21 of the Clayton Act in direct response to the outcry:

> There had been much complaint that a jury trial, to which an accused was entitled if the thing charged against him was a crime, would be denied him if it was called a contempt. Congress felt that substantial rights should not depend upon what appeared to many to be nothing but a play upon words.

Taliaferro v. United States, 290 F. 906, 910 (4th Cir. 1923).[9] Section 21 contains an exemption for actions brought by the United States, but Congress provided for a jury trial in many such actions by including provisions like §882(b) in individual statutes.

Given this history, it would be anomalous to suggest that the inclusion of a civil jury trial provision in §882(b) was meant to strip the district court of all discretion to con-

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[9] The legislative history of §21 confirms this impression:

> That complaints have been made and irritation has arisen out of the trial of persons charged with contempt in the Federal courts is a matter of general and common knowledge. The charge most commonly made is that the courts, under the equity power, have invaded the criminal domain, and under the guise of trials for contempt, have really convicted persons of substantive crimes for which, if indicted, they would have a constitutional right to be tried by a jury. It has been the purpose of your Committee in this Bill to meet this complaint
> . . . .

H. Rep. No. 613, at 6 (1914)(quoted in Frankfurter & Landis, 37 Harv. L. Rev. at 1055); *see also United States v. Pyle*, 518 F.Supp. 139, 152 (E.D. Pa. 1981)(discussing legislative history); 48 Cong. Rec. 8778 (1912)("The courts have, under the guise of contempt of court, had men arrested and tried for crimes without the intervention of a jury") (statement of Rep. Clayton).

sider the procedural consequences of proceeding by injunction rather than by prosecution. Fairly read, §882(b) represents a due process floor in cases where the exercise of judicial discretion nonetheless leads to issuance of an injunction under the CSA. But nothing in §882(b) suggests that Congress meant to foreclose equity courts from weighing the diminished procedural protections available in a civil contempt proceeding when deciding whether to issue an injunction in the first place. As Congress plainly knew, courts in this country have done precisely that for more than a century.

Specifically, in deciding whether to grant an injunction, courts have traditionally considered procedural hardships that a defendant might encounter in equity, as compared to in a criminal proceeding. *See* "Development in the Law -- Injunction, The Changing Limits of Injunctive Relief," 78 Harv.L.Rev. at 1004 (citing cases); W.E. Shipley, "Injunction as Remedy Against Defamation of Person," 47 A.L.R. 2d 715, at §5(b)(1956)(discussing the reluctance of courts to enjoin criminal libel because of reduced procedural protections in equity); *see, e.g., Heber v. Portland Gold Mining Co.*, 172 P. 12, 14 (Colo. 1918)(refusing to issue an injunction that would "deny one cited for contempt a trial by jury in what is in effect a criminal case"). A congressional intent to cabin this well-established rule of equity would have required a clearer statement than §882 provides. *See Hecht*, 321 U.S. at 329 ("We cannot but think that if Congress had intended to make such a drastic departure from the traditions of equity practice, an unequivocal statement of its purpose would have been made").

The concern for procedural hardship is most compelling in cases such as this one, where the proposed injunction is coterminous with a criminal statute, where a compelling necessity defense may well exist, and where members of the OCBC have demonstrated an absolute commitment to serve patients in dire medical need who have no alternative medi-

cal treatment. Because OCBC members have a demonstrated determination to serve patients who have a proven medical necessity for marijuana, the risk of future incarceration for contempt is more than hypothetical. Far from automatically issuing an injunction upon a purported violation of federal law, a district court in such a situation should consider the absence of procedural safeguards, both in the injunction proceeding itself and in any subsequent contempt proceeding.

C. The District Court Should Have Considered, As An Equitable Matter, That A Necessity Defense May Not Be Available In A Subsequent Contempt Proceeding

When the district court decided not to carve out an exception to its injunction for cases of medical necessity, it erroneously assumed that the applicability of a necessity defense could be litigated in a future contempt proceeding. *See Cannabis Cultivators Club*, 5 F.Supp.2d at 1102 ("If . . . the federal government alleges that defendants have violated the injunction . . . the Court can determine if the jury should be given a necessity instruction as a defense to the alleged violation of the injunction"). That assumption is, at the very least, subject to question. This ambiguity provides yet another basis for the Ninth Circuit's decision to remand the district court's refusal to modify the injunction to exclude cases of medical necessity. Regardless of whether any such defense is ultimately recognized under the CSA, the district court should have considered, as part of its equitable calculus, the risk that including cases of medical necessity in its injunction might well forever bar litigation of the medical necessity defense.

As a general matter, of course it is well-settled that the validity of a court order cannot be tested in a contempt proceeding unless the injunction is "transparently invalid." *See*

Walker v. City of Birmingham, 388 U.S. 307, 315 (1967); *United States v. United Mine Workers of Am.*, 330 U.S. 258, 293-94 (1947); *Howat v. Kansas*, 258 U.S. 181, 189-190 (1922). Those accused of contempt can argue lack of jurisdiction, *see Ex Parte George*, 371 U.S. 72, 73 (1962), or substantial compliance, *see Balla v. Idaho State Board of Corrections*, 869 F.2d 461, 466 (9th Cir. 1989), or inability to comply, *see Evans v. Williams*, 206 F.3d 1292, 1299 (D.C.Cir. 2000). To our knowledge, however, *no* federal court has allowed necessity as a defense to contempt. The few courts to have addressed the issue have rejected even considering necessity as a defense to violating an injunction. *See, e.g., Zal v. Steppe*, 968 F.2d 924, 929-30 (9th Cir. 1992)(affirming trial court's evidentiary order excluding necessity defense to contempt).

Under these legal circumstances, the district court was wrong to assume, as part of its equitable calculations, that OCBC would automatically be able to litigate its necessity defense in a subsequent contempt proceeding. Instead, it should have considered the serious possibility that such a defense might be barred in a contempt proceeding brought against OCBC members who chose to violate the injunction. The court's judgment that the defense would best be litigated in a more definite factual setting may have been correct, but it should have compelled the court to circumscribe the injunction to allow distribution of cannabis in cases of medical necessity, leaving the defense itself to be litigated in a subsequent criminal proceeding.

CONCLUSION

For the reasons stated above, the judgment of the court of appeals should be affirmed.

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(18)

No. 00-151

IN THE
Supreme Court of the United States

UNITED STATES,

Petitioner,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE, *et al.*,

Respondent.

On Writ of Certiorari To The United States Court of Appeals For the Ninth Circuit

AMICUS CURIAE BRIEF OF THE MARIJUANA POLICY PROJECT AND RICK DOBLIN, PH.D AND ETHAN RUSSO, M.D. IN SUPPORT OF THE RESPONDENTS

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IDENTITY AND INTEREST OF *AMICI CURIAE*

The Marijuana Policy Project (MPP), Rick Doblin, Ph.D. and Ethan Russo,M.D., respectfully submit this brief as amici curiae in this case. Letters from Petitioner and Respondents

granting consent to the filing of this brief have been filed with this Court.[1]

MPP (www.mpp.org) is a non-profit, public interest advocacy organization representing more than 1,000 seriously ill people throughout the nation who are struggling to obtain legal access to medical cannabis. Since 1995, MPP and several of its seriously ill clients have met with officials from the FDA, the National Institutes of Health, and the National Institute on Drug Abuse (NIDA). MPP representatives have also testified before the National Academy of Sciences' Institute of Medicine (IOM) and the American Medical Association House of Delegates. MPP's clientele, like thousands of other patients nationwide, must choose between suffering or following their doctors' orders to use medical cannabis—even though the latter may result in a federal prison sentence. Consequently, MPP is exhausting all options to provide a legal avenue through which its clients may obtain and use medical cannabis.

Rob Kampia is the co-founder and executive director of MPP.

Rick Doblin has a Ph.D. in Public Policy from the Kennedy School of Government, Harvard University. He is the founder and current director of the Multidisciplinary Association for Psychedelic Studies (MAPS, www.maps.org), a non-profit membership-based research and educational organization and pharmaceutical company that works to develop cannabis and other Schedule I drugs into Food and Drug Administration (FDA)-approved prescription medicines. MAPS helped support the successful five-year struggle of Dr. Donald Abrams, University of California -San

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[1] Pursuant to Rule 37.6, Amici discloses that no counsel for a party authored any part of this brief, nor did any person or entity other than Amici Curiae, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

Francisco, to obtain permission to conduct research into the effects of smoked cannabis in AIDS patients. Dr. Abrams' study, which treated the first patient in 1998, was the first FDA-approved study of the medical use of smoked cannabis in a patient population in twelve years. MAPS holds the only Orphan Drug designation granted by the FDA for any medical use of the cannabis plant itself, specifically in the treatment of AIDS patients suffering from HIV-related wasting syndrome. MAPS thus has a commercial interest in developing the cannabis plant into an FDA-approved prescription medicine for AIDS wasting, and potentially for other clinical indications as well. MAPS is preparing to submit an application to DEA to obtain permission for its own small medical cannabis production facility, to grow high-potency cannabis for FDA-approved protocols.

Ethan Russo, M.D.,is a Clinical Child and Adult Neurologist; Adjunct Associate Professor of Pharmacy, University of Montana, and editor of the *Journal of Cannabis Therapeutics*. Dr. Russo, with the support of MAPS, obtained FDA approval (IND #58,177) to conduct a human pilot study into the risks and benefits of smoked cannabis in patients suffering from treatment-resistant migraines. Despite FDA approval of his protocol, Dr. Russo was unable to conduct his research. NIDA, which holds a monopoly on the supply of cannabis approved by FDA for use in human clinical research, refused to sell any of its cannabis to Dr. Russo for use in his protocol.

SUMMARY OF THE ARGUMENT

The federal government, specifically the NIDA of the U.S. Department of Health and Human Services (HHS), retains a restrictive and unnecessary monopoly over the only supply of cannabis that at this time is allowed to be used in FDA-approved clinical trials. HHS and NIDA have exercised this monopoly over cannabis so as to impede the normal drug

development process contemplated by Congress. Most recently, NIDA and HHS have unreasonably imposed an additional layer of regulatory review over privately funded clinical research with cannabis. No other Schedule I drug has to endure such an obstacle course.

In the instant case, this Court is being asked to decide whether there is a medical cannabis necessity defense to the Controlled Substances Act, 21 U.S.C. 801 *et. seq.* Amici urge the Court to keep in mind that the FDA drug development process, the most direct and appropriate method for authorizing the provision of cannabis to patients with a legitimate, medical need for the drug, has been politically hobbled. The lack of FDA-approval of cannabis as a prescription medicine is due, in large part, to the systematic hindrance of scientific research by governmental agencies over the last several decades. The Court should not rule against a medical necessity defense based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for the medical necessity defense to serve as a "safety net" for a limited number of patients.

THE ARGUMENT

I. THE MEDICAL NECESSITY DEFENSE IS THE ONLY REASONABLE ALTERNATIVE GIVEN THE GOVERNMENT'S OBSTRUCTION OF FDA-APPROVED RESEARCH INTO THE POTENTIAL THERAPEUTIC USES OF CANNABIS

A. An Agency of the Federal Government Has a Monopoly on the Legal Supply of Cannabis for Use in FDA-Approved Research.

The Single Convention on Narcotic Drugs, to which the United States is a Party, regulates the manufacture of

cannabis within the boundaries of the signatory nations.[2] Under Article 23 2(e) of the convention, a private, non-governmental organization can obtain permission from a Party to grow cannabis for licensed medical uses without the Party coming into violation of any of the provisions of the Convention. The non-governmental producer would not need to sell its output to the government and could distribute its stocks for medical purposes to the extent that it was licensed to do so. In order for a non-governmental producer to function in this manner, the government would need to extend formally its exclusive rights to manufacture and trade cannabis for medical purposes to the non-governmental entity.

In the United States, NIDA is the federal agency that has had a monopoly on the supply of FDA-approved research-grade cannabis for use in human subjects.[3] [4] Sponsors of research into the medical uses of cannabis cannot at present manufacture their own supplies of research material but must instead petition to purchase federal supplies at cost from NIDA. However, NIDA's institutional mission is to sponsor research into the understanding and treatment of the *harmful* consequences of the use of illegal drugs and to conduct educational activities to reduce the demand for and use of

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[2] Single Convention on Narcotic Drugs (US Treaty Series Vol. 520, US Treaties and other International Agreements. Vol 18 Part 2, 1967, p. 1407-1431.), which concluded on March 30, 1961, and entered into force in the United States on June 24, 1967. For the text of the treaty, *see* http://www.incb.org/e/ind_ar.htm

[3] NIDA contracts with the University of Mississippi to grow cannabis for research purposes, under the direction of Professor Mahmoud ElSohly. The University of Mississippi facility holds the only license issued by the DEA for the production of cannabis for human consumption.

[4] FDA has not permitted researchers to use seized marijuana for research purposes due to uncertain purity and the inability to conduct subsequent studies with a standardized and replicable product.

these illegal drugs. NIDA's mission makes it a singularly inappropriate agency to be responsible for expeditiously stewarding scientific research into potential *beneficial* medical uses of cannabis. Furthermore, as with many monopolies, the quality of its product is low, [5] and access is restricted.

In contrast, in England, which is also a Party to the Single Convention, the Home Office in 1997 granted a license to GW Pharmaceuticals, a non-governmental for-profit corporation, to grow cannabis for the manufacture of cannabis extracts to be used in clinical trials.[6]

MAPS is preparing to apply to the Drug Enforcement Administration (DEA) for a license to establish a small, medical cannabis production facility to supply high-quality research material to researchers with FDA-approved protocols. This facility will most likely take several years or more to become approved and operational, if ever. For the foreseeable future, NIDA will continue to exert undue control over medical cannabis research as a result of its monopoly over the supply of cannabis.

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[5] MAPS and California NORML conducted a scientific study of the potency of cannabis used by patients across the country. This potency was then compared to the average potency of the cannabis that NIDA provides to the eight remaining patients who are part of the Compassionate Investigational New Drug program. Patients preferred cannabis that was roughly three to four times more potent than what NIDA supplies. The primary advantage of more potent cannabis is that it enables patients to inhale less smoke and particulate matter per unit of therapeutic cannabinoids. Gieringer D. *Medical Cannabis Potency Testing Project*, MAPS 9 (1999) 3:20-22. http://www.maps.org/news-letters/v09n3/09320gie.html

[6] See website of GW Pharmaceutical company's non-profit arm, the UK Medicinal Cannabis Project: http://www.medicinal-cannabis.com/project/main.html

B. FDA-Approved Research into the Therapeutic Uses of Cannabis Has Been Blocked by NIDA.

Ideally, after a physician has determined that a patient has a medical need for the use of the cannabis plant, the patient should be able to obtain it in the form of an FDA-approved prescription medicine that is standardized for purity and potency. For this outcome to be realized, a pharmaceutical company must first submit to FDA sufficient scientific data proving safety and efficacy in a specific patient population, with the data gathered in controlled clinical trials conducted with prior approval of the FDA and DEA. [7] [8]

Despite persisting interest in the medical research community into the exploration of the medical uses of cannabis, not one single patient in the United States received cannabis in the context of an FDA-approved study during the 12-year period between 1986—when the last of the state studies concluded into the use of smoked cannabis in controlling nausea and vomiting in cancer chemotherapy patients[9]—and 1998, when Dr. Donald Abrams at the University of California—San Francisco administered smoked cannabis to the first AIDS patient in his

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[7] See FDA Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products. http://www.fda.gov/cder/guidance/1397fnl.pdf

[8] MAPS and California NORML are sponsoring research into the use of vaporizer technology to heat the cannabis plant but not burn it. Preliminary evidence demonstrates that the vaporizer can release clinically significant amounts of cannabinoids without generating the compounds that come from combustion This is part of an effort to develop non-smoking delivery systems for the cannabis plant.

[9] Randall R. *Marijuana, Medicine & the Law Volume 2*. Washington, DC: Galen Press, 1989, 250. The States were California, New York, New Mexico, Tennessee, Georgia, Michigan and Washington.

groundbreaking study.[10] Dr. Abrams had to struggle for five years to obtain permission to conduct his study, three years of which was after his initial protocol had been approved by FDA. In order to proceed at all, NIDA demanded that Dr. Abrams transform his FDA-approved protocol, designed to assess safety and efficacy in AIDS wasting patients, into a safety study primarily evaluating the risks of cannabis in AIDS patients who did not suffer from AIDS wasting syndrome.[11]

In response to NIDA's reluctance to provide cannabis for medical research into its potential medical uses, the American Medical Association House of Delegates in December 1997 passed the following resolution:

> That the AMA urge the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana. This effort should include: . . . (c) confirming that marijuana of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the Drug Enforcement Agency [sic] who are conducting bona fide clinical research studies that receive Food and Drug Administration approval, regardless of whether or not the NIH is the primary source of grant support.[12]

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[10] Abrams D. Medical Cannabis:Tribulations and Trials.*Journal of Psychoactive Drugs* 30 (Apr-Jun 1998) 2:163-9.

[11] Leshner A. Director of NIDA. Letter to Dr. Donald Abrams. April 19, 1995. http://www.maps.org/mmj/leshner.html; Abrams D. Letter to Dr. Leshner, Director of NIDA. April 28, 1995. http://www.maps.org/mmj/abrams.html.

[12] Council on Scientific Affairs Report 10 - Medical Marijuana, Recommendations, passed by AMA House of Delegates, December 9, 1997.

C. HHS's 1999 Guidelines Restrict Rather than Facilitate FDA-Approved Research.

In December 1999, HHS finally implemented a new written policy regarding the provision of cannabis to FDA-approved researchers, allegedly to expedite FDA-approved medical cannabis research.[13] Rather than announce that NIDA would supply cannabis for free or at cost to all FDA-approved protocols, HHS added yet another layer of bureaucratic review.

HHS's guidelines require sponsors of privately funded and FDA-approved protocols who seek to purchase supplies from NIDA to submit their protocols for review and approval to the Public Health Service (PHS), an additional review process that exists exclusively for cannabis research.[14] HHS guidelines also specified a limited number of medical conditions for which cannabis should be tested, recommended that protocols be designed to prove cannabis equal or superior to existing medications despite FDA's statutory requirement to approve drugs if they are proven safe and efficacious as compared to placebo (since some patients may respond best to a medicine that is not on average equal to or better than other medicines), suggested that researchers conduct only "multi-patient" studies rather than "single-patient" studies which FDA also considers scientifically valid, and discouraged researchers from conducting studies with the goal of getting natural cannabis approved as a prescription medicine. None of these restrictions apply to research with any other substance, even those in Schedule I.

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[13] Guidance On Procedures for the Provision of Cannabis for Medical Research. Department of Health and Human Services. May 21, 1999. http://www.mpp.org/guidelines/hhsguide.html

[14] The new HHS guidelines read, "After submission, the scientific merits of each protocol will be evaluated through a Public Health Service interdisciplinary process." [section III, second paragraph].

John Benson, M.D., principal investigator of the 1999 IOM report on medical cannabis, commented that "it's hard to discern that these guidelines have streamlined existing procedures."[15]

Almost immediately, HHS's policy had a chilling effect on medical cannabis research. In September 1999, Dr. Ethan Russo received FDA approval for a protocol designed to examine the medical uses of cannabis in treatment-resistant migraine patients, an indication for which cannabis was utilized in mainstream Western medicine between 1842 and 1942.[16] In February 2000, NIDA refused to supply Dr. Russo with the necessary cannabis, based on criticisms of the protocol design by the PHS reviewers.[17] Since Dr. Russo's protocol was approved by FDA and would have been privately funded, the decision by PHS and NIDA not to provide the cannabis at cost effectively halted the standard FDA drug development process.

For the foreseeable future, medical research with cannabis will proceed only as far and as fast as NIDA and HHS permit, regardless of the willingness of FDA to allow clinical trials to move forward.

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[15] McMahon, P., Oregon, Alaska Identify Legal Marijuana Users on State-Issued Cards. USA Today, May 24, 1999, A 4.

[16] McCormick C. Director of FDA Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Ethan Russo. Sept. 21, 1999. Re: IND #58,177. See also, Russo, E.B., Cannabis for Migraine Treatment: The Once and Future Prescription?: An Historical and Scientific Review, *Pain* 36(1):3-8, 1998, or available at: http://www.druglibrary.org/crl/pain/Russo%2098%20Migraine_%20Pain.pdf

[17] Mann L. Public Health Service, Center for Scientific Review. Summary Statement: Cannabis in Acute Migraine Treatment Project. Letter to Dr. Russo. February 1, 2000. http://www.maps.org/mmj/russo1199/02010001.html

D. HHS's Policy Makes it More Difficult to Research Cannabis Than Any Other Drug, Including All Other Schedule I Drugs.

Within the last ten years, FDA has approved several privately funded protocols involving the use of Schedule I substances such as MDMA (Ecstasy),[18] psilocybin,[19] and ibogaine.[20] Each of these studies was or will be conducted with compounds obtained from private, non-governmental DEA-licensed manufacturers. The lack of an independent source of cannabis for use in FDA-approved clinical trials is an aberration and not the norm for Schedule I drugs.

E. Given the Difficulty of Conducting FDA-Approved Research, It is Unlikely that the FDA Will Be Able to Approve Cannabis as a Prescription Medicine in the Near Future, If Ever.

In January 1997, in response to the passage of Proposition 215 in California, the White House Office of National Drug Control Policy commissioned IOM to conduct a one-million-dollar study into the therapeutic uses of cannabis. In March

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[18] Approved November 5, 1992. IND #39,383. A Phase 1 dose-response safety study conducted by Dr. Charles Grob, Harbor UCLA. The MDMA was manufactured under DEA license by Dr. David Nichols, Dept. of Medicinal Chemistry, Purdue University.

[19] ND # 56,530. McCormick C. Director of FDA's Division of Anesthetics, Critical Care and Addiction Drug Products. Letter to Dr. Francisco Moreno. Sept 17, 1998. This protocol was approved but put on hold until a source of psilocybin could be arranged. MAPS has arranged for Organix, Inc. of Woburn, MA to manufacture the psilocybin

[20] On August 25, 1993, the FDA Drug Abuse Advisory Committee meeting recommended approving the Phase 1 dose- response safety study proposed by Dr. Juan Sanchez-Ramos and Deborah Mash, Ph.D., U. of Miami Medical School. The ibogaine for this study was imported by the researchers from Europe, with DEA approval.

1999, IOM released its report [21] which had the following to say about the likelihood of the FDA being able to approve cannabis as a prescription medicine:

> [R]esearch funds are limited, and there is a daunting thicket of regulations to be negotiated at the federal level (those of the Food and Drug Administration, FDA, and the Drug Enforcement Administration, DEA) and state levels. [p. 137]
>
> Some drugs, such as marijuana, are labeled Schedule I in the Controlled Substance Act, and this adds considerable complexity and expense to their clinical evaluation. [p. 194]
>
> From a scientific point of view, research is difficult because of the rigors of obtaining an adequate supply of legal, standardized marijuana for study. [p. 217]
>
> In short, development of the marijuana plant is beset by substantial scientific, regulatory, and commercial obstacles and uncertainties. [p. 218]
>
> [D]espite the legal, social, and health problems associated with smoking marijuana, it is widely used by certain patient groups. [p. 7]

Consequently, patients who are already medicating with cannabis under their doctors' supervision have little hope that the FDA drug-approval process will result in cannabis being made available as a prescription medicine. This pessimistic outlook has nothing to do with the actual therapeutic potential of cannabis, and has everything to do with political obstacles that have subverted the FDA drug-approval process.

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[21] Joy J, Watson S, Benson J (eds.): *Cannabis and Medicine: Assessing the Science Base*, Washington, DC: Institute of Medicine, National Academy Press, 1999. http://stills.nap.edu/books/0309071550/html

F. The Executive Branch Disregarded the Institute of Medicine's Recommendation to Provide Immediate Access to Medical Cannabis on a Case-By-Case Basis.

The 1999 IOM report made the following recommendations about research into the medical uses of cannabis:

> [I]t will likely be many years before a safe and effective cannabinoid delivery system, such as an inhaler, is available for patients. In the meantime there are patients with debilitating symptoms for whom smoked marijuana might provide relief.
>
> Until a non-smoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting. One possible approach is to treat patients as n-of-1 clinical trials (single-patient trials), in which patients are fully informed of their status as experimental subjects using a harmful drug delivery system, and in which their condition is closely monitored and documented under medical supervision.
>
> Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions: failure of all approved medications to provide relief has been documented; the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs; such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness... (p. 7-8)[22]

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[22] *Ibid.*

Two months later, HHS released its medical cannabis research guidelines, which formally took effect in December 1999. HHS's policy reads, in part:

> HHS intends to direct its program toward multi-patient clinical studies. As previously determined by [PHS], single-patient requests for marijuana raised a number of concerns including the fact that the single-patient IND process would not produce useful scientific information and we do not foresee that they would be supported under this program.[23]

Hence, the executive branch has not only shown its willingness to block congressional intent, but it has also disregarded the findings of the IOM of the National Academy of Sciences, chartered by Congress in 1863 to advise federal agencies.

II. BECAUSE THE FDA DRUG DEVELOPMENT PROCESS IS NOT WORKING AS CONGRESS INTENDED, PATIENTS WHO FOLLOW THEIR DOCTORS' ORDERS TO OBTAIN CANNABIS THROUGH ALTERNATIVE MEANS SHOULD BE PERMITTED TO OFFER A MEDICAL NECESSITY DEFENSE

Thousands of seriously ill people nationwide are already using cannabis to treat their medical conditions. Many—if not all—of these patients would prefer to receive their medication through pharmacies. Short of that, many patients would appreciate the opportunity to participate in FDA-approved research as a means of gaining temporary, legal access to cannabis. Having been thwarted by bureaucratic obstacles impeding recourse through the FDA, medical cannabis

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[23] Guidance On Procedures for the Provision of Cannabis for Medical Research. Department of Health and Human Services. May 21, 1999, section IV, fourth paragraph.

patients currently have no practicable option but for the medical necessity defense.

Patients whose physicians consider their use of cannabis to be necessary for the treatment of their illnesses must risk criminal sanctions to obtain the relief they deserve. As the Court considers the viability of the medical necessity defense, it should consider that the lack of sufficient scientific data from FDA-approved controlled clinical trials to justify FDA-approval of cannabis as a prescription medicine is in large part due to the hindrance of research over the last several decades. Moreover, HHS's 1999 policy imposed yet another layer of regulatory review over privately funded clinical research with cannabis, more burdensome than for research with any other drug.

Given the difficulties of conducting FDA-approved research into the medical uses of cannabis because of the past and continuing supply problems and HHS' unique and restrictive guidelines, it is unrealistic to expect that patients who have a legitimate medical need will be able to obtain temporary legal access to cannabis via FDA-approved research in any substantial way. And, even if the FDA were disposed to approve cannabis as a prescription medicine many years from now, the Court should allow the medical necessity defense to be raised in the meantime.

The Court should not rule against a medical necessity defense based on the illusion of a well-functioning FDA-approval process. Executive branch obstructionism has made it necessary for the medical necessity defense to serve as a "safety net" for a limited number of patients.

CONCLUSION

For the foregoing reasons, Amici ask this Court to affirm the judgment of the court of appeals.

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February 20, 2001

No.: 00-151

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In the Supreme Court of the United States

United States of America, petitioner

vs.

Oakland Cannabis Buyers' Cooperative
et al., respondents

On writ of certiorari to
the United States Court of Appeals
for the Ninth Circuit

MOTION TO ALLOW FILING OF *AMICUS* BRIEF

and

AMICUS CURIAE BRIEF FOR AFFIRMANCE IN SUPPORT OF RESPONDENTS

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BEST AVAILABLE COPY

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Amicus Trippet argues that the exemption of medically-necessary cannabis from the injunction should be not just affirmed but broadened to apply to all cannabis for bona-fide medical purposes when recommended by a physician.

THE CSA AS APPLIED IS UNCONSTITUTIONAL: p. 3

Unless the government has a compelling federal interest in prohibiting medical use of cannabis, then it violates patients' and states' rights as construed by this Court.

COMMERCE CLAUSE AND STATES' RIGHTS: p. 5

Congress has no constitutional power to impose federal prohibition of a drug in states that want to allow it, unless an amendment (like the 18th) is enacted authorizing that.

PATIENT'S RIGHT TO NEEDED MEDICINE: p. 20

The right to a medically-necessary abortion even after fetal viability implies that the right to medically-necessary treatment is even broader than the right to abortion.

CRUEL AND UNUSUAL PUNISHMENT: p. 24

Any punishment for supplying cannabis for medical needs is unconstitutionally excessive and disproportionate, since there is no wrong done nor intended.

EQUAL PROTECTION WITH OTHER MEDICINES: p. 25

Congress cannot have intended that the Attorney General be free to refuse to recognize medical use of cannabis when physicians recommend it and states legalize it.

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REQUEST FOR LEAVE TO FILE *AMICUS* BRIEF:

Sudi Pebbles Trippet hereby requests leave to file the attached *Amicus Curiae* brief in support of affirmance.

Consent has been requested from the parties. The Acting Solicitor General has consented in writing on behalf of the United States (see Appendix at A-1) but counsel for Respondents has withheld consent, giving no reasons.

Amicus Trippet believes that unless the government has a compelling federal interest in banning medical cannabis, constitutional caselaw protects its use and furnishing for bona-fide medical purposes; and that the Controlled Substances Act (CSA) must be construed so as not to conflict with those rights (or be voided insofar as it conflicts).

Amicus is one of many patients who have the right to use cannabis under California's Prop. 215 (see A-2), but do not, or might not, qualify under the necessity defense.

She uses cannabis to prevent and relieve migraine headaches, and has her physician's written recommendation for this, which is all she needs under current state law.

Amicus chooses cannabis in part because it is significantly safer than any other migraine drug; but this is not sufficient under the necessity defense as it usually is understood (and has been understood in this case) since she can't prove all other migraine drugs are unreasonably dangerous, ineffective or otherwise unavailable.

Amicus is also a member of Respondent Oakland Cannabis Buyers' Cooperative (OCBC), but like the vast majority of members she is effectively unrepresented in this case.

The case now pending in this Court is that of a few patients who are Intervenors in the underlying case, each of whom is qualified to use cannabis under both state law and the common-law necessity defense.

Their counsel argue that the CSA was not intended to exclude a necessity defense in exceptional cases like theirs.

Perhaps thinking the smallest victory is the easiest to win, they have presented arguments, mainly on statutory construction, that are calculated to benefit only the few patients with a medical "necessity" for cannabis; and they have essentially ignored all arguments that would benefit more patients, including most constitutional arguments.

Since counsel for Respondents have been unwilling to provide *Amicus* an advance draft of their brief or inform her of what they plan to put in it, she does not know what their brief will include; but based on the litigation so far, she believes they plan to continue to exclude all arguments that would tend to benefit any large number of patients.

They have, in fact, gambled everything on the opposite strategy; they argue that so few patients would qualify under a necessity defense as to be insignificant and thereby not in significant conflict with the spirit of the CSA.

That is, Respondents' counsel (who actually are Intervenors' counsel) have chosen to sacrifice the interests of perhaps 99% of OCBC's membership, in hope of improving the chances of the tiny minority they actually represent.

What is most ironic about this is that by refusing to make any arguments that could benefit the entire membership of OCBC, Respondents' counsel have left out the arguments most likely to succeed at all.

For instance, although the new President is on record as believing a state should have the right to legalize medical cannabis, and it is clear from *U.S. v. Lopez* (1995) 514 US 549 and *U.S. v. Morrison* (5/15/2000) ___ US ___ that a majority of this Court believe that the Commerce Clause does not allow federal "police" powers over local activities, Respondents' counsel have barely mentioned states' rights and have not argued a single case in support.

Most notably, they have ignored *Linder v. U.S.* (1925) 268 US 5, the controlling case on the limits of federal power to control practice of medicine within a state, which construed the fore-runner of the CSA as inapplicable to intra-state supplying of a patient with a small quantity of a drug for bona-fide medical purposes.

They also ignore the controlling case on a patient's right to medically-necessary treatment, *Colautti v. Franklin* (1979) 439 US 379, which held that the right to choose such a treatment is even broader than the right to choose abortion; and that physicians must be given broad discretion to decide what is best for their patients' health.

Amicus therefore seeks to argue that the exemption to the injunction should be not just upheld but broadened.

Unless the government has a compelling federal interest in prohibiting medical use of cannabis, then insofar as the CSA is construed to have this effect, it violates patients' and states' constitutional rights as construed by this Court in numerous cases over the past two centuries.

Intervenors deserve to prevail in this case, and would deserve to prevail even if they had something less than a medical "necessity" for cannabis; it should be sufficient to have any bona-fide medical purpose, such as to avoid the need to use more hazardous alternatives (even if the alternatives are not unreasonably hazardous).

(1) *Linder v. U.S.* (1925) 268 US 5 found that the forerunner of the CSA could not bar doctors from supplying small quantities of drugs to patients for bona-fide medical purposes, because Congress lacks the constitutional authority to control the practice of medicine within a state.
U.S. v. Lopez (1995) 514 US 549 held that the cases that expanded Congress' Commerce Clause powers did not alter the rule that Congress has no police power over local acts without a substantial involvement of interstate commerce.

(2) *Roe v. Wade* (1973) 410 US 113 found constitutional protection for the right to choose one medical treatment, abortion, with no need to claim medical-necessity and with no suggestion that the constitution gave abortion any more protection than it gives other medical choices.
Colautti v. Franklin (1979) 439 US 379 extended *Roe* by ruling that even after fetal viability, although there is no longer a general right to choose abortion, physicians must still be allowed broad discretion to provide abortions when they find it to be in the best interest of a patient's health.

(3) *Weems v. U.S.* (1910) 217 US 349 requires dismissal of a charge if the minimum penalty would be excessive and disproportionate to the offense; but supplying cannabis for medical use does no offense to anyone, so any penalty will by definition be excessive and disproportionate.
The *Enmund v. Florida* (1982) 458 US 782 majority held that penalties are unconstitutionally cruel unless based on wrongful intent, while the dissent argued that harm to victims also matters; but those who supply cannabis for medical use neither intend nor cause any harm to anyone.

(4) *Yick Wo v. Hopkins* (1886) 118 US 356 held equal protection includes equal laws without unjust discrimination between those in similar circumstances; but the CSA lets the Attorney General ban natural cannabis yet allow synthetic cannabis and many more dangerous drugs.

School of Magnetic Healing v. McAnnulty (1902) 187 US 94 found that Congress could not have intended such an absurd result as placing an administrative official in charge of deciding the efficacy of medical treatments on which the medical community has divided opinions.

U.S. v. Carolene (1938) 304 US 144 requires voiding a statute that has become irrational due to changes in facts since its enactment; but the CSA was based on there being no significant current medical use of cannabis, and that fact has been reversed since 1970.

There will be no need to decide these issues if the CSA is construed to be inapplicable in the absence of a significant involvement of interstate commerce; or inapplicable if and when there is a significant medical usage of cannabis.

But insofar as the CSA is construed as taking away the right of California to allow medical use of cannabis, it violates states' rights as much as a federal law regulating the practice of medicine within a state.

Also, insofar as the CSA was intended to take away a patient's right to obtain the safest or otherwise best drug for her medical condition, it is as unconstitutional as a law that takes away her right to obtain an abortion.

Further, insofar as the CSA is held to penalize medically necessary acts, or any victimless acts done for bona-fide medical purposes, it is as unconstitutionally cruel as a law that punishes people who have done nothing wrong

And insofar as the CSA authorizes the Attorney General to discriminate against natural cannabis and in favor of synthetic cannabis, it is as unconstitutional as a law that authorizes him to discriminate against small businesses.

The Court should therefore remand the question to the district court to determine what compelling federal interest the government has to balance the patient's and state's.

(1) If Congress could not prohibit intra-state supplying of alcohol until a constitutional amendment was enacted to authorize this, then Congress cannot impose prohibition of a medicine in states that want to allow it, until and unless a constitutional amendment is enacted authorizing that.

Medical cannabis was legal by prescription under state and federal law until the 1970 enactment of the Controlled Substances Act and its state equivalents.

Before 1970 it was well understood that the states had the exclusive right to regulate local medical practice and that federal jurisdiction over medicine only existed if there was an involvement of interstate commerce.

Since 1970 the federal government has taken the position that the CSA authorizes it to imprison any distributors or growers of any quantity of cannabis even for bona-fide medical purposes, no matter how local the activity and no matter how extreme or well-verified the need.

One reason to doubt that Congress intended that result is that such penalties would appear worse than just excessive; they would seem to be simply *purposeless*.

Another reason is that it makes more sense to assume Congress only intended to control acts having a significant impact on interstate commerce, since it had so long been understood that the federal government could not control intra-state medical practices and could not bar doctors from supplying drugs to patients in small amounts for bona-fide medical purposes.

The case most directly on point, *Linder v. U.S.* 268 US 5, which has never been overturned, construed the 1914 Harrison Narcotic Law as not intended to apply to such intra-state activities since the constitutionality of a federal law against such activities would at best be very doubtful:

> "Congress cannot, under the pretext of executing delegated power, pass laws for the accomplishment of objects not entrusted to the Federal Government.
>
> "And we accept as established doctrine that any provision of an act of Congress ostensibly enacted under power granted by the Constitution, not

naturally and reasonably adapted to the effective exercise of such power but solely to the achievement of something plainly within power reserved to the States, is invalid and cannot be enforced."

"Obviously, direct control of medical practice in the States is beyond the power of the Federal Government." (*Linder* 268 US at 17-8)

Linder was typical of two centuries of caselaw; from *Gibbons v. Ogden* (1824) 9 Wheat. 1 to *U.S. v. Lopez* (1995) 514 US 549, this court has consistently agreed that Congress' power to regulate commerce "among" the states does not include the power to regulate drug (or any other) commerce occurring entirely within a single state.

Gibbons said Congress has no power over commerce:

"which is completely internal, which is carried on between man and man in a State, or between different parts of the same State, and which does not extend to or affect other States."

"Comprehensive as the word 'among' is, it may very properly be restricted to that commerce which concerns more States than one....

"The enumeration presupposes something not enumerated; and that something, if we regard the language or the subject of the sentence, must be the exclusively internal commerce of a State."

"...inspection laws....form a portion of that immense mass of legislation, which embraces every thing within...a State, not surrendered to the general government: all which can be most advantageously exercised by the States themselves.

"Inspection laws, quarantine laws, health laws of every description, as well as laws for regulating the internal commerce of a State...are component parts of this mass."

"...quarantine and health laws...are considered as flowing from the acknowledged power of a State, to provide for the health of its citizens." (*Gibbons* at 9 Wheat. 194-5, 203, 205)

Gibbons voided a New York law that granted a monopoly of steamboat traffic in New York waters used for inter-state and foreign shipping. By contrast, *Veazie v. Moor* (1853) 14 How. 568 upheld a similar Maine law, because it applied to a river accessible only to intra-state shipping:

> "...the power vested in Congress by article 1st, section 8th of the Constitution, was not designed to operate upon matters...which are essentially local in their nature and extent." (*Veazie* 14 How. at 574)

The *License Tax Cases* (1866) 5 Wall. 462 upheld a federal tax on sales of liquor and lottery tickets on the ground that it was a tax (and hence was authorized by the Revenue Clause), and not a regulation or prohibition under the Commerce Clause, which would not have been valid:

> "...very different considerations apply to the internal commerce or domestic trade of the States.
>
> "Over this commerce and trade Congress has no power of regulation nor any direct control.
>
> "This power belongs exclusively to the States." (5 Wall. at 470-1)

By contrast, *U.S. v. Dewitt* (1870) 9 Wall. 41 voided a federal law restricting (but not taxing) sale of naphtha and illuminating oils as beyond the constitutional authority over interstate commerce, holding that Congress has no power "to prohibit trade within the limits of a State"; and that the Commerce Clause has always been understood:

> "...as a virtual denial of any power to interfere with the internal trade and business of the separate states..." (*Dewitt* 9 Wall. at 44)

The reason for giving Congress power over interstate commerce was once well-understood, not to create a police power nor a national planned economy, but to prevent the trade barriers that generally existed across national boundaries and that would exist across state boundaries if the states were free to create them:

> "...the object of vesting in Congress the power to regulate commerce...among the States was to

insure uniformity of regulation against conflicting and discriminating State legislation. (*County of Mobile v. Kimball* (1880) 102 US 691 at 697)

"The design and object of that power, as evinced in the history of the Constitution, was to establish a perfect equality amongst the several States as to commercial rights, and to prevent unjust and invidious distinctions, which local jealousies or local and partial interests might be disposed to introduce and maintain." (*Veazie* 14 How. at 574)

Coe v. Errol (1886) 116 US 517 considered the question of when goods first come under the Commerce Clause:

"There must be a point of time when they cease to be governed exclusively by the domestic law and begin to be governed and protected by the national law of commercial regulation, and that moment seems to us to be a legitimate one for this purpose, in which they commence their final movement for transportation from the State of their origin to that of their destination."

"It is true, it was said in the case of *The Daniel Ball,* 10 Wall. 557, 565: 'Whenever a commodity has begun to move as an article of trade from one State to another, commerce in that commodity between the States has commenced.'

"But this movement does not begin until the articles have been shipped or started for transportation from the one State to the other." (116 US at 525, 528)

Kidd v. Pearson (1888) 128 US 1 ruled that a state has a right to decide whether sale and manufacture of alcohol were to be prohibited within it, because the federal power to regulate commerce:

"...does not comprehend the purely domestic commerce of a State which is carried on between man and man within a State or between different parts of the same state...".

"If it be held that the [Commerce Clause] includes the regulation of all such manufactures as are in-

tended to be the subject of commercial transactions in the future, it is impossible to deny that it would also include all productive industries that contemplate the same thing.

"The result would be that Congress would be invested, to the exclusion of the States, with the power to regulate, not only manufactures, but also agriculture, horticulture, stock raising, domestic fisheries, mining - in short, every branch of human industry." (128 US at 17, 21)

As of 1888, such a conclusion still seemed an absurdity.

The *Lottery Case* (1903) 188 US 321 expanded Congress' Commerce Clause authority to include police powers over perceived threats to public morals, but upheld a federal law against interstate trafficking in lotteries only because it did not attempt to suppress lotteries within a single state:

"...[it] does not assume to interfere with traffic or commerce in lottery tickets carried on exclusively within the limits of any State, but has in view only commerce of that kind among the several States.

"It has not assumed to interfere with the completely internal affairs of any State, and has only legislated in respect of a matter which concerns the people of the United States." (188 US at 357)

Jacobson v. Massachusetts (1905) 197 US 11 upheld the state's right to decide whether to require vaccination:

"The authority of the State to enact this statute is to be referred to what is commonly called the police power - a power which the State did not surrender when becoming a member of the Union under the Constitution.

"...this court...has distinctly recognized the authority of a state to enact quarantine laws and 'health laws of every description;' indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other States."

"The safety and health of the people of Mass-

achusetts are, in the first instance, for that Commonwealth to guard and protect.

"They are matters that do not ordinarily concern the National Government." (197 US at 25, 38)

The *Employers' Liability Cases* (1908) 207 US 463 was one of many about federal laws protecting workers from extreme exploitation - laws that could be authorized by the 13th Amendment as much as by the Commerce Clause.

As the Court described it at 496, the challenged law involved "regulation of the relation of master and servant" (*i.e.*, employer and employee), and it plainly had a purpose in spirit closer to stopping "involuntary servitude" than to protecting interstate freedom of trade. However, the government did not invoke the 13th Amendment.

Two Justices opined in *dictum* that the Commerce Clause did not authorize such interference in employment matters; they also found the statute invalid because it applied to intra- as well as inter-state commerce, with which three other Justices concurred, making a majority.

Four dissenting Justices wanted to uphold the statute, but only because they construed it as inapplicable to intra-state activities. All nine Justices agreed that Congress had no power over a state's internal commerce. As one put it,

"...I agree that the Congress has not the power directly to regulate the purely internal commerce of the States, and...I understand that to be the opinion of every member of the court." (207 US at 505, Moody, J., dissenting)

Another case with 13th-Amendment implications, *Hoke v. U.S.* (1912) 227 US 308, upheld the White Slave Act ban on interstate transporting of women for immoral purposes as a measure against "enslavement in prostitution".

But again, transportation across state lines was involved:

"Let an article be debased by adulteration, let it be misrepresented by false branding, and Congress may exercise its prohibitive power.

"It may be that Congress could not prohibit the manufacture of the article in a State.

"It may be that Congress could not prohibit in

all of its conditions its sale within a State.
"But Congress may prohibit its transportation between the States, and by that means defeat the motive...of its manufacture." (227 US at 322)

Hammer v. Dagenhart (1917) 247 US 251 went to the extreme of holding that Congress couldn't even control the manufacture of goods intended for interstate commerce:

"Over interstate transportation, or its incidents, the regulatory power of Congress is ample, but the production of articles, intended for interstate commerce, is a matter of local regulation.
"When the commerce begins is determined... by its actual delivery to a common carrier for transportation, or the actual commencement of its transfer to another state."

"The grant of power to Congress over the subject of interstate commerce was to enable it to regulate such commerce, and not to give it authority to control the States in their exercise of the police power over local trade and manufacture.
"The grant of authority over a purely federal matter was not intended to destroy the local power always existing and carefully reserved to the States in the Tenth Amendment to the Constitution."

"...the commerce power....is one to control the means by which commerce is carried on, which is directly the contrary of the assumed right to forbid commerce from moving and thus destroy it as to particular commodities." (247 US at 272-3, 269)

The Court therefore voided a federal law banning interstate commerce in products of companies that employ child labor below a stated age or in excess of stated hours.

Congress responded by enacting a stiff tax on companies that violate child-labor standards. In the *Child Labor Tax Case* (1922) 259 US 20, the Court voided it, holding that the Revenue Clause, like the Commerce Clause, couldn't be used to give power to Congress over intra-state affairs:

"To give such magic to the word 'tax' would be to break down all constitutional limitation of the

powers of Congress and completely wipe out the sovereignty of the States." (259 US at 38)

Since child labor comes about as close as you can get to "involuntary servitude", and the 13th Amendment clearly overrides state autonomy, it is not clear why the government didn't claim authority under that provision; if they had, later caselaw might have gone very differently.

Lambert v. Yellowley (1926) 272 US 581 upheld a federal law that limited (but didn't prohibit) prescriptions of alcohol for medical use. A four-justice dissent argued:

"Congress...cannot directly restrict the professional judgment of the physician or interfere with its free exercise in the treatment of disease.
"Whatever power exists in that respect belongs to the states exclusively." (*Lambert* 272 US at 598)

The *Lambert* majority at 593, citing *Everard's Breweries v. Day* 265 US 545, acknowledged that Congress generally can't enact such laws, but ruled that the 18th Amendment gave Congress the power to limit prescriptions of alcoholic beverages "although affecting subjects which, but for the Amendment, would be entirely within state control".

The CSA's predecessor was upheld in *U.S. v. Doremus* (1919) 249 US 86 and in *Nigro v. U.S.* (1927) 276 US 332 on the theory that it was a tax, not a prohibition:

"In interpreting the Act, we must assume that it is a taxing measure, for otherwise it would be no law at all.
"If it is a mere act for the purpose of regulating and restraining the purchase of the opiate and other drugs, it is beyond the power of Congress and must be regarded as invalid..." (276 US at 341)

Schechter v. U.S. (1935) 295 US 495 unanimously rejected the theory that Congress has authority over everything that affects interstate commerce, since in effect this would mean that Congress had authority over everything, period:

"If the commerce clause were construed to reach all enterprises and transactions which could be said

to have an indirect effect upon interstate commerce, the federal authority would embrace practically all the activities of the people and the authority of the State over its domestic concerns would exist only by sufferance of the federal government.

"...the authority of the federal government may not be pushed to such an extreme as to destroy the distinction, which the commerce clause itself establishes, between commerce 'among the several States' and the internal concerns of a State." (295 US at 546, 550)

Even *NLRB v. Jones & Laughlin Steel* (1937) 301 US 1, which gave an expansive reading to the Commerce Clause, still warned that the limits of Congress' powers:

"...must be considered in the light of our dual system of government and may not be extended so as to embrace effects upon interstate commerce so indirect and remote that to embrace them...would effectually obliterate the distinction between what is national and what is local and create a completely centralized government." (301 US at 37)

Santa Cruz Fruit v. NLRB (1938) 303 US 453 also gave the Commerce Clause an expanded reading, but still denied Congress any powers over intra-state commerce with only a remote or insignificant effect on interstate commerce:

"...where federal control is sought to be exercised over activities which separately considered are intrastate, it must appear that there is a close and substantial relation to interstate commerce in order to justify the federal intervention...

"However difficult in application, this principle is essential to the maintenance of our constitutional system. The subject of federal power is still 'commerce,' and not all commerce, but commerce with foreign nations and among the several States." (303 US at 466)

U.S. v. Darby (1941) 312 US 100 further expanded the Commerce Clause, overturning *Hammer v. Dagenhart* and

upholding a federal minimum-wage and maximum-hours law, applied not only to goods shipped interstate but also to the production of a commodity all or part of which is intended for interstate commerce; but *Darby* expanded the Clause only where there is a "**substantial effect on interstate commerce**", 312 US at 119, with no suggestion that this could also apply to purely local, small-scale activities.

Wickard v. Filburn (1942) 317 US 111 gave an even more expansive reading to the Commerce Clause, allowing Congress to limit the size of wheat crops.

But the expansiveness of *Wickard* has often been greatly exaggerated, including by Justice Souter's lead dissent in *U.S. v. Morrison* (2000) ___ US ___, ___, which claims it applied to "**ostensibly domestic, noncommercial farming.**"

Filburn, a commercial farmer, had grown 23 acres of wheat, which was 12 acres more than his allotment under the Agricultural Adjustment Act of 1938. Some of this was for sale and some for feeding his own livestock but almost all of it was grown for purely commercial purposes.

The court held that farms of such size, collectively, had sufficient effect on the national market that Congress could impose a maximum number of acres of wheat per farm.

Thus *Wickard*, one of few rulings allowing Congress so much power over local activities, only concerns crops that are many times larger than a family's annual consumption (even though not large in comparison to other farms). The Court made clear that the Act didn't affect small farms:

> "**Exemption from the applicability of quotas was made in favor of small producers....on which the acreage planted to wheat is not in excess of fifteen acres.**" (317 US at 92).

Wickard did not consider and therefore does not control the case of a patient who grows (or a doctor who supplies) a small quantity sufficient for her own personal needs.

Justice Douglas' dissent in *Maryland v. Wirtz* (1968) 392 US 183 at 204 argued that *Wickard* meant "**All activities affecting commerce, even in the minutest degree...may be regulated and controlled by Congress...**"

The *Wirtz* majority rejected that interpretation:

> "Neither here nor in *Wickard* has the Court declared that Congress may use a relatively trivial impact on commerce as an excuse for broad general regulation of state or private activities..." (392 US at 197 fn 27)

Perez v. U.S. (1970) 402 US 146 gave perhaps the most expansive reading to the Commerce Clause, upholding a federal law against loan-sharking that applied to even the smallest transactions; *Perez* didn't give Congress power over local crime in general but rather only found that Congressional findings justified the conclusion that loan-sharking was controlled by interstate organized crime:

> "It appears...that loan sharking in its national setting is one way organized interstate crime holds its guns to the heads of the poor and the rich alike and syphons funds from numerous localities to finance its national operations." (402 US at 146)

In *U.S. v. Bass* (1971) 404 US 336, the Court construed a federal law against felons possessing guns as requiring a showing of connection to interstate commerce:

> "Because its sanctions are criminal and because, under the Government's broader reading, the statute would mark a major inroad into a domain traditionally left to the States, we refuse to adopt the broad reading in the absence of a clearer direction from Congress."
>
> "...unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance.
> "Congress has traditionally been reluctant to define as a federal crime conduct readily denounced as criminal by the States." (404 US at 339, 349)

Even after the CSA was enacted, the States have still been understood to be in charge of regulating health within their borders; as *Whalen v. Roe* (1977) 429 US 589 put it:

> "It is...well-settled that the State has broad police

powers in regulating the administration of drugs by the health professions." (429 US at 603, fn. 30)

U.S. v. Rutherford (1979) 442 US 544 upheld a ban on interstate commerce in an unproved cancer drug, Laetrile, rejecting a statutory-construction argument that it was unreasonable if applied to terminally ill patients.

The Court did not consider any constitutional arguments, but still made clear why there was no Commerce Clause or states' rights issue, the ban being only on interstate trade:

"Seventeen States have legalized the prescription and use of Laetrile for cancer treatment within their borders, and similar statutes have been defeated in 14 other States." (442 US at 554, fn. 10)

This Court has not forgotten the reasons for not having a centralized government; it explained them at length just a decade ago in *Gregory v. Ashcroft* (1991) 501 US 452:

"This federalist structure of joint sovereigns preserves to the people numerous advantages. It assures a decentralized government that will be more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive by putting the States in competition for a mobile citizenry."

"Perhaps the principal benefit of the federalist system is a check on abuses of government power."

"Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front." (501 US at 458)

Since there is no issue here of failure to pay some tax, nor any issue of importing from outside the country, nor any other apparent basis for federal jurisdiction, it would appear that the government must claim that every time a

patient grows one cannabis plant or even one dose is supplied to her, it has enough indirect effect on interstate commerce that the federal government has jurisdiction.

U.S. v. Lopez went to great lengths to reject that theory. *Lopez* voided a federal law penalizing possession of a gun in a school zone. The dissenters argued that the perceived harmful effects of gun possession in school zones were so severe as to make the question a federal issue, Congress having jurisdiction under the Commerce Clause on the theory that anything so harmful to society as a whole must by definition have some effect on interstate commerce.

The majority denied that the constitutional power to "**regulate Commerce...among the several States**" (Art. 1, ¶8, cl. 3) included power over intra-state activities (which, in *Lopez'* case, weren't even "commerce").

The lead opinion by Chief Justice Rehnquist summarized the history of Supreme Court Commerce Clause jurisprudence and concluded that it has never agreed to such an expansive reading of that clause as would give Congress authority over activities with a very indirect and insubstantial effect on interstate commerce.

The majority's main reasoning was that such a reading would give the federal government police powers over even the most localized (and non-commercial) of activities, which would be redundant to or supersede the state's jurisdiction, and which would mean the Commerce Clause had created a centralized national government with general police powers - which it plainly wasn't meant to do.

> "The Government admits, under its 'costs of crime' reasoning, that Congress could regulate not only all violent crime, but all activities that might lead to violent crime, regardless of how tenuously they relate to interstate commerce....
>
> "Similarly, under the Government's 'national productivity' reasoning, Congress could regulate any activity that it found was related to the economic productivity of individual citizens....
>
> "Under the theories that the Government presents ...it is difficult to perceive any limitation on federal power, even in areas such as criminal law enforcement or education where States historically have been sovereign.

"Thus, if we were to accept the Government's arguments, we are hard pressed to posit any activity by an individual that Congress is without power to regulate." (514 US at 564)

Justice Thomas' concurrence in *Lopez* traces the history of the court's Commerce Clause jurisprudence from the 1700s to 1936, showing that for the first 150 years the clause was understood to differentiate between interstate and intra-state commerce, creating federal jurisdiction over the one but reserving the other to the states.

Justice Thomas believes that even a "substantial effect" on interstate commerce is not sufficient to provide federal jurisdiction, since there are many crimes that indirectly have such an effect but which the Commerce Clause plainly was not intended to create federal jurisdiction over.

"We have said that Congress may regulate not only 'Commerce...among the several States'...but also anything that has a 'substantial effect' on such commerce.

"This test, if taken to its logical extreme, would give Congress a 'police power' over all aspects of American life."

"Although we have supposedly applied the substantial effects test for the past 60 years, we *always* have rejected readings of the Commerce Clause and the scope of federal power that would permit Congress to exercise a police power; our cases are quite clear that there are real limits to federal power." (514 US at 584, Thomas, concurring; emphasis in original)

An even more recent case, *U.S. v. Morrison* (5/15/2000) ___ US ____, rejected the theory that Congress has power over violent crime based on its aggregated effects:

"Given...petitioners' arguments, the concern that we expressed in *Lopez* that Congress might use the Commerce Clause to completely obliterate the Constitution's distinction between national and local authority seems well founded."

"If accepted, petitioners' reasoning would allow Congress to regulate any crime as long as the nationwide, aggregated impact of that crime has substantial effects on employment, production, transit, or consumption."

"We accordingly reject the argument that Congress may regulate noneconomic, violent criminal conduct based solely on that conduct's aggregate effect on interstate commerce.

"The Constitution requires a distinction between what is truly national and what is truly local....

"In recognizing this fact we preserve one of the few principles that has been consistent since the Clause was adopted." (*Morrison* ____ US at ____)

But if Congress has no power to prohibit *violent* local acts such as rape, what power can they have to prohibit *non-violent* local acts such as the practice of medicine?

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So much of the expansion of the Commerce Clause has been for purposes of preventing economic exploitation of those in powerless positions (child-labor, "white slave" traffic, unorganized labor, etc.), that 13th-Amendment "involuntary servitude" issues seem at least as relevant as any theory that interstate commerce is affected.

Morrison, too, can be seen as a 13th-Amendment-related case; it is no stretch to say that rape is a kind of slavery.

But however analysed, the expanded-Commerce-Clause cases mostly involved laws intended to protect someone from crime or exploitation; they are not very relevant precedents regarding whether a state still has the right to control the practice of medicine within its borders.

Other expansions of the Commerce Clause have resulted from cheap transport causing the economy as a whole to become more national; but even if 23-acre farms and loan-sharks of all sizes can be presumed to have an interstate impact, *Linder* has never been overturned as to supplying small amounts of drugs to patients for medical purposes.

There is not just a Commerce Clause issue but also a very strong states' rights issue here, since California has decided it wants medical use of cannabis to be legal here.

States have sometimes been denied the right to prohibit medical treatments, but *Amicus* knows of no case where a state has been denied the right to *allow* a treatment.

States were free to allow abortion even before *Roe v. Wade;* states are now free to allow Laetrile or assisted suicide. Why can't a state allow medical use of cannabis?

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(2) If the constitution protects a woman's right to abort a pregnancy despite the loss of a nascent life, a thing of undisputedly great value, then it must at least equally protect her right to take cannabis to abort a migraine headache attack, a thing of indisputably negative value.

Medically-necessary abortion was already generally if not universally legal, long before *Roe; Roe* recognized not just the rights of a few exceptional patients, but of *all*.

If *Roe* is taken as giving abortion greater protection than most other medical treatments, it would be fair to say that the enacters of the Constitution never intended that.

But it would be more fair to understand *Roe* as holding that the general standards of medical freedom also apply to abortion (despite the valid state interest in the fetus' life).

The right not to be deprived of life, liberty or property without due process, is enough textual support for medical freedom to justify requiring the government to show that it has a compelling interest in banning a medical treatment and that its law is narrowly tailored to serve that interest.

Roe at 410 US 153 gave as one argument for the right to abortion, that it can be safer than full-term pregnancy.

Full-term pregnancy is not unreasonably hazardous for most women, but even a small risk is enough under *Roe* that all women have a right to refuse to bear it.

Amicus has a similar right to choose the safest drug for her condition, even if the other drugs are not unreasona-

bly hazardous, unless the government can show what compelling interest it has in denying her this choice.

If the *Roe* court had considered that child-bearing is also notoriously painful, it might have added that it would be unconstitutionally cruel to punish a woman for refusing to undergo such pain. Likewise, migraines are painful enough that refusal to suffer them can hardly be punishable.

Textual support for a constitutional right to abortion can also be found in the 13th Amendment ban on involuntary servitude. To be forced to bear a child against one's will is a kind of slavery, but it is in principle little different from being forced to bear headache pain or other illness because of an unjustified prohibition of the best available medicine.

The *Roe* court itself held that a woman's right to choose a medical treatment necessary to her life or health is even broader than her general right to choose abortion; that is, even after the fetus is viable (when there is no longer a general right to choose abortion under *Roe*), she still has a right to choose abortion if her health requires it:

> "...subsequent to viability, the State in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." (*Roe v. Wade* 410 US at 164-5)

In *U.S. v. Vuitch* (1971) 402 US 62 and again in *Doe v. Bolton* (1973) 410 US 179, this Court upheld the adequacy of medical-necessity exemptions to abortion restrictions; but in *Colautti v. Franklin* (1979) 439 US 379, this Court found such an exemption to be inadequate, explaining:

> "The contested provisions [in *Vuitch* and *Doe*] had been interpreted to allow the physician to make his determination in the light of all attendant circumstances - psychological and emotional as well as physical - that might be relevant to the well-being of the patient.
> "The present statute does not afford broad discretion to the physician." (*Colautti* 439 US at 394)

Thus this Court has not only found a right to choose a medically-needed treatment that is broader than the right to choose abortion, this Court has also found that this must not be a narrow exemption (as in the common-law necessity defense), but rather must allow the physician to have "broad discretion" to consider all factors revelant to the patient's "emotional as well as physical...well-being".

Roe held that, even where there was no significant health hazard to the mother, her right to choose this particular medical treatment was so fundamental that even the state's interest in the fetus' life wasn't enough to outweigh it.

Two justices dissented in *Roe*, as in *Doe*, its companion case; but both dissenters made clear that they would see it differently if the mother's health were at risk:

> "If the Texas statute were to prohibit an abortion even where the mother's life is in jeopardy, I have little doubt that such a statute would lack a rational relation to a valid state objective..." (*Roe*, 410 US at 173, Rehnquist, dissenting)

> "It is my view...that the Texas statute is not constitutionally infirm because it denies abortions to those who seek to serve only their convenience rather than to protect their life or health." (*Doe*, 419 US at 222, White, dissenting)

Thus it appears that all nine Justices agreed abortion is constitutionally-protected when medically necessary; why should medically-necessary cannabis be less protected?

There are only two possible inferences:

Either: the Constitution gives abortion such preferred status that a woman has a right to choose it, even after fetal viability, even for mere "emotional...well-being", yet no right to choose cannabis even if her life depends on it.

Or: patients *always* have a right to choose what's best for their health, and no law may take away this right unless narrowly-tailored to serve a compelling interest.

Roe applied the general "strict scrutiny" standard:

> "Where certain 'fundamental rights' are involved, the Court has held that regulation limiting these rights may be justified only by a 'compelling state interest.'" (410 US at 155)

This case involves "life" as well as "liberty", but either would be enough to require strict-scrutiny review.

"Liberty" is sometimes taken as meaning the freedoms considered fundamental by Anglo-American common law tradition when the Constitution was enacted.

By this standard, medical use of cannabis is protected, since medical use of all herbs was always legal under the common law. And medically-necessary cannabis is even more protected, since the very existence of a "common-law necessity defense" shows there was a well-established right to disobey laws when needed to avoid a greater evil.

"Liberty" is also sometimes construed in autonomy terms ("...**our notions of liberty are inextricably entwined with our idea of physical freedom and self-determination...**", *Cruzan v. Director* (1990) 497 US 261 at 287, O'Connor, concurring), by which Respondents should likewise prevail.

Neither common law nor the logic of autonomy justifies giving the right to choose to *refuse* a treatment any more protection than the right to choose to *have* it.

Specifically as to medically-necessary treatment, the right to *refuse* lifesaving treatment has been almost universally recognized, while the right to *have* lifesaving treatment has inexplicably not been so well recognized.

Washington v. Glucksberg (1997) 521 US 702 found no right to choose life-ending treatment, based on a long-standing Anglo-American tradition of treating assisted suicide as murder rather than as a "liberty".

But even if "life, liberty and property" don't include a right to death, they at least include a right to "*life*"!

So if patients have a right to *refuse* medically-necessary treatment even to the point of committing (unassisted) suicide, how can their right to *have* medically-necessary treatment – *i.e.*, to choose to *live* – be any less?

Patients must also have a right to choose medication to avoid pain, nausea, blindness or other suffering.

Glucksberg did not decide that issue since Washington's law allowed palliative care (see 521 US at 737, O'Connor, concurring, and 791, Breyer, concurring); but common law decides it, since the medical use of drugs to relieve suffering was never a crime under the common law.

Amicus does not claim that common law or autonomy principles give her absolute freedom of choice over her body or health; only that she has the right to have her medical interests balanced against whatever legitimate counter-interests the government may have.

Jacobson v. Massachusetts (1905) 197 US 11 upheld a compulsory-vaccination law, but agreed that people have a right to challenge the justification for such a law:

> "There is, of course, a sphere within which the individual may assert the supremacy of his own will and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will." (197 US at 29)

If the CSA really was intended to criminalize cannabis even for bona-fide medical use and even when medically necessary, it is as unconstitutional as a law criminalizing medically necessary abortion - unless the government has some legitimate interest, compelling enough to justify the avoidable pain, avoidable nausea and avoidable deaths.

The Court should therefore either construe the CSA as inapplicable to bona-fide medical use of cannabis, or else remand the case for determination of whether the government has a legitimate (federal) interest sufficiently compelling as to outweigh the interests of the patient.

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(3) If the government cannot show a compelling interest in prohibiting medical use of cannabis, then any penalty for supplying it to a patient for bona-fide medical purposes is excessive and disproportionate, and therefore would be unconstitutionally cruel and unusual punishment.

Weems v. U.S. 217 US at 349 held that "**punishment for crime should be...proportioned to the offense**".
But medical use of cannabis does no apparent offense to any known interest, so any penalty for supplying it for medical use is necessarily disproportionate and excessive.

In *Enmund v. California* 458 US at 800 the majority held "**criminal penalties to be unconstitutionally excessive in the absence of intentional wrongdoing**" or "**moral guilt**".

The dissent argued that in addition to intent, punishment should also be proportionate to the harm done:

> "...**the magnitude of the punishment imposed must be related to the degree of the harm inflicted on the victim, as well as to the degree of the defendant's blameworthiness.**" (*Enmund* 458 US at 800, O'Connor dissent)

But there is zero "harm inflicted on the victim" when someone grows or supplies cannabis for medical use.
And as to "intentional wrongdoing", those who supply cannabis for medical purposes have zero "moral guilt".

Therefore, if the government cannot show a legitimate purpose for prohibiting medical use of cannabis, then insofar as the CSA is construed to apply to supplying it for medically-necessary or other bona-fide medical purposes (including self-supply by growing it), any penalty it imposes is excessive and disproportionate, and thus unconstitutionally cruel punishment; and the resulting and intended deprivation of medicine is no less cruel.

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(4) **Even if Congress enacted the CSA based on evidence that there was no significant medical use of cannabis in 1970, it did not authorize the Attorney General to ignore any revival of medical use of cannabis as has occurred, nor to substitute his judgment for that of physicians, nor to unreasonably allow synthetic but not natural cannabis.**

To the extent Congress meant to authorize the Attorney General to discriminate among medicines, the result is reminiscent of the San Francisco ordinance struck down in *Yick Wo v. Hopkins* 118 US 356, whose:

> "tendency...if not...purpose...is to drive out of business all the numerous small laundries, especially those owned by Chinese, and give a monopoly...to the large institutions established...by...large associated Caucasian capital" (*Yick Wo* 118 US at 362)

The CSA as it has been applied has had the similar "tendency...if not...purpose" of driving out of business the many small producers of natural cannabis, including many non-whites, while giving a monopoly to the "large associated Caucasian capital" corporations that sell the patented competing drugs including the synthetic form of cannabis known as Marinol (= Marijuanaoil) or dronabinol.

Another way the old San Francisco ordinance resembles the CSA as it has been applied, is that both are uncompromising prohibitions rather than reasonable regulations:

> "It does not profess to prescribe regulations ...nor require...precautions and safeguards... nor in any other way attempt to promote their safety and security without destroying their usefulness" *Yick Wo* at 372

And insofar as the CSA empowers the Attorney General to discriminate among medicines, as *Yick Wo* put it:

> "Though the law be fair on its face and impartial in appearance, yet, if it is applied...with...an unequal hand, so as practically to make unjust... discriminations between persons in similar circumstances...the denial is still within the prohibition of the Constitution." *Yick Wo* at 373

Mugler v. Kansas (1887) 123 US 623 upheld a state's right to pursue interests such as "public health" by prohibiting sale of alcohol (the law allowed it for medical use). But at 660 the Court wrote that the "power does not exist with the whole people to control rights that are purely and exclusively private"; and that courts must judge whether privacy rights are violated by a law:

> "It does not at all follow that every statute enacted ostensibly for the promotion of those [public] ends, is to be accepted as a legitimate exertion of the police power of the state....

> "If, therefore, a statute purporting to have been enacted to protect the public health, the public morals or the public safety, has no real or substantial relation to those objects...it is the duty of the courts to so adjudge..." *Mugler* 123 US at 661

Whether there was no significant medical usage of cannabis in 1970 may be debated but is now moot.

Since Congress authorized the Attorney General to reschedule cannabis to allow prescriptions if a medical use developed, it plainly did not consider this impossible.

However reasonable the CSA may have been in 1970, the situation regarding medical use of cannabis has changed; this case is now in this Court only because there has been such an enormous increase in the medical use of cannabis, that California voters felt the need to make it a "right".

> "the constitutionality of a statute predicated upon the existence of a particular state of facts may be challenged by showing to the court that those facts have ceased to exist." (*Carolene* 304 US at 153)

This is not changed by Congress having delegated to the Attorney General the decision whether to recognize that the facts have changed. While it is not clear that Congress even has the power to delegate to the executive branch the decision of what the legal status of a thing shall be, it certainly cannot delegate any power it doesn't have.

Nothing in the CSA justifies the conclusion that Congress intended that the Attorney General have the power to tell physicians whether there is a medical use for cannabis; if that were the purpose, it would have made more sense to give this power to the *Surgeon* General instead.

Rather, Congress may be assumed to have meant it to work the other way around: the physicians would tell the Attorney General if a medical use for cannabis existed, and the Attorney General would just accept their opinion, acting as a mere clerk, not as National Health Commissar.

But insofar as the CSA empowers the Attorney General to decide whether medical use of cannabis is desirable (and

not just whether it is bona-fide medical use), it puts a medical decision in the hands of someone with no medical credentials who, as chief prosecutor, can't be impartial.

And insofar as the CSA gives a Washington bureaucrat with no medical credentials the power to make medication decisions overriding the patient's and her doctor's choices, it is structurally irrational; that is, there is no possible rational basis for thinking the Attorney General is the right person to be making *Amicus'* medical decisions.

The Attorney General's interpretation of the CSA has a remarkably similar historic precedent.

School of Magnetic Healing v. McAnnulty (1902) 187 US 94 concerned a fraud statute that the Postmaster General interpreted as allowing him to ban the School of Magnetic Healing from receiving mail.

The Court thought Congress mustn't have intended this, since it would be absurd to put an official with no relevant credentials in charge of deciding the value of a treatment:

> "It is still in an empirical stage, and enthusiastic believers in it may regard it as entitled to a very high position in therapeutics, while many others may think it absolutely without value or potency in the cure of disease.
>
> "Was this kind of question intended to be submitted for decision to a Postmaster General, and...that he might decide the claim to be a fraud...?
>
> "As the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud." (187 US at 105)

If California physicians (and voters) believe cannabis safe and effective for various conditions, equal protection with magnetic healing requires the same decision here.

"Was this kind of question intended to be submitted for decision to [an Attorney] General...?"

There could be no rational basis for giving the Attorney General the power to decide if the medical use of cannabis is bona-fide, nor whether to exclude it from interstate commerce as fraudulent; and even less, to impose his view by controlling the local practice of medicine within a state that has voted to declare medical use of cannabis a "right".

Nor is there any possible rational basis for giving the Attorney General the power to decide that the physicians who recommend cannabis are mistaken; "...the efficacy of any special method is certainly not a matter for the decision of the [Attorney] General..."

While the government shouldn't be allowed to prohibit a medicine without a sufficient compelling interest, it doesn't even have a rational basis for prohibiting physicians from prescribing natural cannabis while allowing prescriptions of synthetic cannabis and other more hazardous drugs.

It also has no rational basis for discriminating against medical cannabis compared with laetrile, which states are free to legalize as many have done (*Rutherford* 442 US at 554 fn. 10); assisted suicide, which states can legalize as Oregon has done (*Glucksberg* 521 US at 709 fn. 7); abortion, which states could legalize even before *Roe;* or alcohol, which states were free to legalize before the 18th Amendment and have been since it was repealed.

Such unequal protection demands explanation.

– – –

CONCLUSION: **The Attorney General's interpretation of the CSA is irrational and constitutionally dubious at best since nothing in the record shows a federal interest sufficient to outweigh the interests of the state or patient.**

Congress anticipated that there might be significant medical usage of cannabis in the future, and therefore authorized the Attorney General to re-schedule it to allow prescriptions if this occurred (as it has).

But nothing in the CSA implies that the Attorney General was authorized to substitute his judgments for those of the medical profession or his will for that of the states.

As he has interpreted it, the CSA authorizes him to control the local practice of medicine in the states, against their wishes; to deny physicians the right to prescribe the medicine they believe best; and to deny patients the medicine that is best for them, even at the cost of their lives.

One reason to doubt that interpretation is that there is no apparent reason why Congress would want to give the Attorney General such power over the practice of medicine or over the internal affairs of a state.

Another reason is that Congress may be assumed to have been aware of *Linder* and other constitutional caselaw, and not to have intended to give the Attorney General powers that Congress itself had already been denied.

If the CSA gives the Attorney General such powers, this Court should remand for consideration of whether there is a sufficient federal interest to outweigh the state's under the Commerce Clause; whether there is a compelling interest to outweigh the patient's under the Due Process Clause; whether the CSA's penalties are cruel and unusual punishment as applied to cannabis for medical use; and whether there is a rational basis for discriminating against medical cannabis compared to other medical treatments.

But the constitutional issues need not be decided if it is assumed that Congress intended that the Attorney General re-schedule cannabis if and when there was a revival of its medical usage; and did not intend to authorize him to substitute his views for that of physicians or states.

In that event, the medical-necessity exemption to the injunction should be affirmed; and the case remanded with instructions to enlarge the exemption to include all physician-approved medical purposes as per *Linder*.

Respectfully submitted February 19, 2001.

Sudi Pebbles Trippet
amicus in pro. per.

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ACTING SOLICITOR GENERAL'S CONSENT TO FILING:

U.S. Department of Justice
Office of the Solicitor General
Washington D.C. 20530

February 15, 2001

Also via telefax 707-937-3160

Pebbles Trippet
Box 338
Albion Ca 95410

Re: United States v. Oakland Cannabis Buyer's Cooperative et al., No. 00-151

Dear Ms. Trippet,

As requested in your letter of February 14, 2001, I hereby consent to the filing of a brief amicus curiae on behalf of Sudi Pebbles Trippet in the above-styled case.

Sincerely,

Barbara D. Underwood
Acting Solicitor General

cc: William K. Suter, Esquire
Clerk
Supreme Court of the United States
Washington D.C. 20543

PROPOSITION 215 (HEALTH & SAFETY CODE 11362.5)

SECTION 1. Section 11362.5 is added to the Health & Safety Code to read:

11362.5 (a) This section shall be known and may be cited as the Compassionate Use Act of 1996.

(b) (1) The people of the State of California hereby find and declare that the purposes of the Compassionate Use Act of 1996 are as follows:

(A) To ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana in the treatment of cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief.

(B) To ensure that patients and their primary caregivers who obtain and use marijuana for medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.

(C) To encourage the federal and state governments to implement a plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana.

(2) Nothing in this act shall be construed to supersede legislation prohibiting persons from engaging in conduct that endangers others nor to condone the diversion of marijuana for nonmedical purposes.

(c) Notwithstanding any other provision of law, no physician in this state shall be punished, or be denied any right or privilege, for having recommended marijuana to a patient for medical purposes.

(d) Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary care-giver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

(e) For the purposes of this section, "primary care-giver" means the individual designated by the person exempted under this act who has consistently assumed responsibility for the housing, health, or safety of that person.

SECTION 2. If any provision of this measure or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of the measure which can be given effect without the invalid provision or application, and to this end, the provisions of this measure are severable.